Diffused Errors along Technology Spillovers: Evidence from the 510(k) Medical Device Market

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Abstract

We examine the diffusion and consequences of technical errors through spillovers using the predicate list in the 510(k) program in which a new device is proved substantially equivalent to existing ones (i.e., predicates). We match a recalled device with its unrecalled "sibling" and find that the follow-on devices being equivalent to a recalled device are more likely to be recalled (and have more adverse events), especially when the former's manufacturers are more likely to copy technical errors from the recalled device. Such diffused errors negatively influence recalled device manufacturers' growth while providing competitors with opportunities for market shares and inventions.

Keywords: Technology spillovers, recalls, error diffusion, medical devices, 510(k) premarket notification

JEL Classification: G18, I18, L51, O38

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1. Introduction

Technology spillovers and transfers drive economic growth as aggregate productivity increases through prior innovations and inventions being learned, improved, and extended by subsequent innovators (Caballero and Jaffe, 1994; Keller, 2002; Bloom, Schankerman, and Van Reenen, 2013; Aghion and Jaravel, 2015; Arque-Castells and Spulber, 2022). Due to well-documented "path dependence" in technological development, the successes and failures of prior experimentations help guide the direction of subsequent innovation activities (Rosenberg, 1976; Galasso and Schankerman, 2015).[1] However, any undetected errors and flaws in a particular technology may also pass down to subsequent technologies that are based on or mimicking the former, resulting in the diffusion of technical errors and flaws ("diffused errors" henceforth).

Such diffused errors may later create substantial economic losses and even threaten public health. A prominent example is the Y2K problem, which was caused by programmers' conventional use of a six-digit date format to save storage.[2] Another important example is asbestos, which was used to produce a wide variety of materials and products before its dangers became well-known.[3] However, to the best of our knowledge, the diffused errors resulting from technology spillovers and transfers have not been studied on a large scale for their impacts and economic consequences. One of the major challenges in this direction is the lack of comprehensive data that enable the identification of both technical diffusions and errors. In this study, we consider a novel setting based on the FDA's 510(k) premarket notification program for medical devices (more details are provided in the Internet Appendix Section A) to provide empirical evidence and new insights into this research topic.

In the U.S., spending on medical devices consistently accounts for over 5 percent of total national health expenditures (Donahoe, 2021). To be marketed in the U.S., all medical devices, unless exempt under FDA regulations, are subject to one of the two types of FDA premarket reviews – premarket approval (PMA) and 510(k) premarket clearance. PMA requires a full-round review, usually with clinical trial data, to determine whether a new device is reasonably safe and

[1] Such a cumulative feature is reinforced by the network effect (David and Bunn, 1988) and/or the increasing-return pattern in some technologies (Arthur, 1989).
[2] https://www.nationalgeographic.org/encyclopedia/Y2K-bug/
[3] The World Health Organization estimated the health and financial costs associated with asbestos in the report, which is available at: https://www.euro.who.int/data/assets/pdf_file/0003/194133/RB-Asbestos-Mtg-Report-Bonn-2012.pdf

effective, and takes a long time until the final approval. 510(k), on the other hand, only requires the new device to be proved substantially equivalent to another legally marketed device, called "predicates", and takes approximately one-third of the review time relative to PMA.[4] For simplicity, we label new medical devices approved by PMA as "PMA devices" and those cleared by 510(k) as "510(k) devices" throughout the paper.

In general, moderate-risk medical devices go through either PMA or 510(k) (Stern, 2017; Grennan and Town, 2020; Rogers, 2023). Due to the shorter approval time, lower costs, and fewer requirements for clearance, 510(k) has become the dominant mechanism to market a new medical device in the U.S. (31%);[5] only about 1% of medical devices are approved through PMA (Zuckerman, Brown, and Nissen, 2011). Figure 1 presents a graphical illustration of the total number of 510(k) devices vs. PMA devices marketed in the U.S. over time. The number of 510(k) devices is around 3,000 per year while that of PMA devices is around 30.

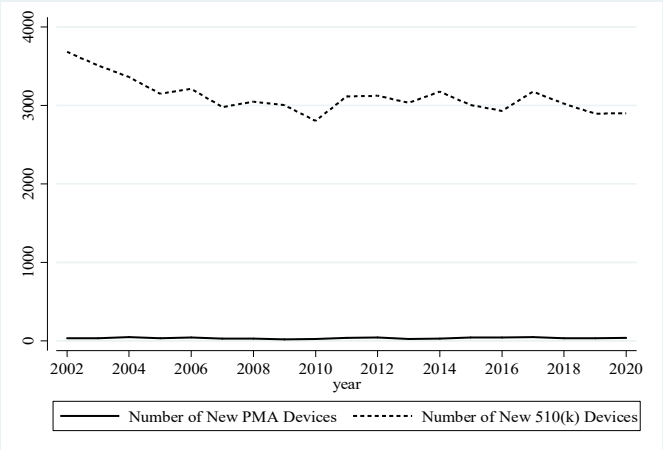


Figure 1. Numbers of 510(k) and PMA Devices

The figure presents the total number of 510(k) devices vs. the total number of PMA devices marketed in the U.S. over time. The dashed line refers to the number of 510(k) devices, and the solid line refers to the number of PMA devices.

A device cleared through 510(k) is required to provide a list of its predicates as substantially equivalent in safety and efficacy. This list of predicates of a 510(k) device allows us to track its

[4] See the reports from Government Accountability Office (GAO) regarding medical device review time at https://www.gao.gov/assets/gao-04-1022.pdf and https://www.gao.gov/assets/gao-09-190.pdf. Longer review times, however, do not necessarily lead to better approval decisions. For example, Stern (2017) finds that approval times for PMA devices are largely unrelated to technological novelty. In addition, Chandra, Kao, Miller, and Stern (2021) examine the effect of the FDA's Breakthrough Therapy Designation (BTD) program and find that the program shortened clinical development times by 24 percent without compromising drug safety.

[5] https://www.gao.gov/assets/gao-09-190.pdf

technological antecedents multiple steps back in history and provides the paper trail of technology spillovers and transfers.[6] We collect a total of 1,568 PMA devices and 83,386 510(k) devices from the FDA's website. Although medical device data are available from 1960, our sample period starts in 2002 because predicate information and recall data are only available from that year. The most important information for each 510(k) device is the list of predicates on the summary of a 510(k) premarket notification, which requires either electronic text processing or manual reading from scanned documents drafted in a non-standard way (see the Internet Appendix Section B). After cleaning and standardizing manufacturer names, our full sample comprises 44,625 510(k) devices with complete predicate information, produced by 11,666 unique manufacturers during the 2002-2021 period.

As the medical literature uses recalls to reflect the quality and risk of medical devices (Zuckerman, Brown, and Nissen, 2011; Somberg, McEwen, and Molnar, 2014; Rogers, 2023), we use the recall records of medical devices to capture technical errors that may have diffused to their follow-on inventions. We find that 10.98% of 510(k) devices have been recalled, while only 0.98% of PMA devices have been recalled during our sample period. This stark contrast in recall rates first alludes to the possibility of technical errors diffusing to follow-on inventions among 510(k) devices relative to PMA devices. More interestingly, we find an increase in recall rates over generations (starting from PMA) among 510(k) devices, which provides preliminary support to our proposition that technical errors diffuse and intensify over the generations.

For causal inferences on technical errors diffusing, we first create "sibling pairs" as follows: for every recalled 510(k) device, we find its siblings that have never been recalled and share the same unrecalled predicates as the recalled device.[7] In this sibling pair of devices coming from the same technology base (i.e., unrecalled predicates), only the recalled device carries technical errors. Thus, it is reasonable to argue that the device recall is likely *unexpected* (rather exogenous than inherited) because (i) the predicate of the siblings is not recalled (and thus does not likely carry technical errors) and (ii) the potential legal consequences and impacts on firm reputation from expected recalls are substantial (Jovanovic, 2021). In the second step, we compare the recall ratio

[6] An alternative approach to collect information related to technology spillovers is to resort to patents covering all new devices. However, not all medical devices are patented, and we are unaware of any publicly available data source for the connection between medical devices and related patents. Some research groups are working on this direction (Argente, Baslandze, Hanley, and Moreira, 2020; de Rassenfosse and Zhou, 2020).

[7] Our sibling-pairing method is motivated by the "twin discoveries" of Bikard (2020) and Marx and Hsu (2022).

of the *follow-on* devices that follow the recalled device (i.e., subsequent devices that list the latter as a predicate) to that of follow-on devices that follow its unrecalled sibling. A higher recall ratio of subsequent devices following the recalled one will substantiate the diffusion of technical errors, all else being equal.

Our regression analysis shows that the follow-on devices of a recalled device are more likely to be recalled than those following its unrecalled siblings, given all other device and manufacturer characteristics being controlled. In terms of economic magnitude, being a follow-on device of a recalled device is associated with an approximately 10 percentage-point higher recall likelihood. This pattern remains robust to using alternative empirical designs and proxies. To further ensure that sibling pairs of devices come from the same technology base and likely lead to similar subsequent technologies, we construct a sample in which the sibling-pair devices need to have at least one follow-on device that list *both* devices as predicates and find consistent results.

We also examine the heterogeneity in predicate recalls and find a significant increase in follow-on device recalls when predicate recalls may cause more serious injuries or deaths, when they are more related to technical issues than non-technical issues that are less inheritable, or when the lag between follow-on devices and their predicates is shorter. All these results support pass-down technical errors in 510(k) devices.

We are aware of alternative explanations including device heterogeneity, manufacturer quality, and precautionary recalls. Device heterogeneity, such as our sibling pairs being fundamentally different in terms of technology complexity, has been mitigated to some degrees by device-fixed effects. We further address this issue by restricting our sample to a smaller set of follow-on devices (and their paired predicates) that are much more homogeneous in technologies. While manufacturer quality may also explain our results, it should have been mitigated by our use of device-fixed effects that absorb manufacturer fixed effects. In addition, we directly address this issue by including manufacturers' time-varying recall rates as an additional control variable in our regressions. We find consistent results.

We acknowledge that follow-on device manufacturers may initiate precautionary recalls due to negative customer sentiment (e.g., Freedman, Kearney, and Lederman, 2012) rather than diffused errors in their products. To separate this alternative explanation from diffused errors, we implement the following tests. First, we examine the recall propensity of follow-on devices in two

cases: the follow-on device and its recalled predicate (i.e., one of the siblings) are produced by the same manufacturer vs. different manufacturers. It is worth noting that these two scenarios are subject to both diffused errors and customer sentiment but to *different* degrees: the case based on different manufacturers is less subject to diffused errors. We find a greater recall propensity of follow-on devices for the same-manufacturer case, which supports the existence of the error diffusion mechanism because a follow-on device is more likely to inherit technical components and know-how from a predicate when it is made by the same manufacturer.

Second, we further divide the sample of different manufacturers' follow-on devices into two groups based on the technological proximity between manufacturers of predicates and follow-on devices. We find that the positive relation between predicates' and follow-on devices' recalls is stronger in the group of high technological proximity, which corroborates the effect of diffused errors. Nevertheless, we cannot completely rule out the possibility of the customer sentiment mechanism in which manufacturers recall their products (regardless of whether the recalled predicates are by the same manufacturers or not) just to restore customers' confidence or to maintain brand image, not because fixing technical errors is necessary.

We then examine how predicate recalls are related to follow-on devices' adverse events, which are free from the customer sentiment effect and have important implications for public health. We collect the Manufacturer and User Facility Device Experience (MAUDE) data that include adverse event reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters (health care professionals, patients, and consumers). Using the number of MAUDE reports for each device, we find that a follow-on device receives more adverse event reports when its predicate is recalled during the period between its approval and its predicate's recall event. Also, the magnitude of the effect is greater if the recalled predicate is from the same manufacturer or from a different manufacturer that has high technological proximity with the follow-on device manufacturer. These results further support the existence of the error diffusion mechanism which may pose a threat to public health.

We also analyze how predicate recalls influence subsequent innovation performance and strategies of follow-on device manufacturers, which has implications for technological progress and economic growth. We find that predicate recalls encourage the same manufacturers or those in close technological proximity to pivot their innovation and diversify their product portfolios,

which echoes the within-firm substitution effect of Galasso and Luo (2022) and serves as evidence for less exploitative innovation strategies. In contrast, recalls from different manufacturers are associated with more focused product portfolios, especially for those that are technologically distant, which further supports the substitution effect.

We also examine how predicate recalls influence follow-on devices' impact on subsequent inventions (Everhart, 2021). We find that the number of citations that the follow-on devices receive (as the predicate of subsequent devices) *decreases* when the follow-on devices are produced by the same manufacturer as the recalled predicate but *increases* when produced by different manufacturers, especially those with low technological proximity to the manufacturer of the recalled predicate. These results support pass-down technical errors to be the main reason for the reduced impact of follow-on inventions.

Finally, we examine Tobin's q and sales growth for follow-on device manufacturers that experience predicate recalls, to highlight the economic impact of diffused errors on firms. We match firm names in our manufacturer list to firm names in the Compustat database to collect their financial and accounting information. When we separate predicate recall events into the same and different manufacturer cases as discussed earlier, we find intuitive results that, in the same-manufacture case, follow-on device manufacturers' Tobin's q and sales growth drop significantly. More interestingly in the different manufacturer case, we find that Tobin's q and sales growth of follow-on devices' manufacturers increase, especially for manufacturers that are *not* technologically close to the predicate manufacturer. This result is consistent with a substitution effect among competitors (Ball, Macher, and Stern, 2018). We interpret this finding as the competing manufacturers, particularly those with relatively low risk of diffused errors, having an opportunity to take over the markets previously occupied by the manufacturers of recalled products.

Our paper adds to the literature in several ways. First, this research offers new insights to the literature on technology spillovers and transfers by substantiating diffused errors in medical devices as an unintended consequence that intensifies with the externalities and networking effects. The diffused errors we present are distinct from another prominent negative externality issue – the business-stealing effect (Aghion and Howitt, 1992; Bloom, Schankerman, and Van Reenen, 2013) – and call for a more comprehensive and balanced analysis of the role of technology diffusion in economic growth. In addition, as exemplified by the Y2K problem and the prevailing use of

asbestos, diffused errors may lead to serious concerns because once a single technology dominates a market, its errors will be disseminated economy-wide and could result in systematic failure. Thus, government efforts to standardize technologies or to facilitate technology diffusion may inadvertently promote flawed technologies despite their intention to mitigate wasteful R&D (Katz and Shapiro, 1985; David, 1987; Arthur, 1989).

From a broader perspective, this paper is related to the literature on how innovation and knowledge are accumulated and extended. We exploit a unique setting of the predicate listing in the 510(k) premarket notification program to track technology diffusion, which offers new metrics to this literature that has largely relied on patent citations (Jaffe, Trajtenberg, and Henderson, 1993; Acemoglu, Akcigit, and Kerr, 2016), teamwork (Wuchty, Jones, and Uzzi, 2007; Uzzi, Mukherjee, Stringer, and Jones, 2013), and licensing (Arque-Castells and Spulber, 2022). Using recall events in a sibling-matched sample, we also present a new shock to knowledge flows, which differs from but complements prior studies based on paper retraction (Azoulay, Furman, Krieger, and Murray, 2015), patent invalidation (Galasso and Schankerman, 2015, 2018), and biomaterial deposit (Furman and Stern, 2011).

Finally, our investigation delivers large-scale empirical evidence for the higher recall rates of medical devices cleared through the 510(k) premarket notification program, echoing the concerns raised in Zuckerman, Brown, and Nissen (2011), Somberg, McEwen, and Molnar (2014), and Day, Park, Rozenshteyn, Owusu-Sarpong, and Gonzalez (2016) and highlighting the program's limitations. More importantly, we provide a plausible explanation for the higher recall rates of 510(k) devices and present the economic losses associated with these recalls.[8] Furthermore, our novel evidence on subsequent innovation offers a new perspective to the literature on the economic impact of product recalls, which tend to focus on the impact on itself (Jarrell and Peltzman, 1985; Jovanovic, 2021) and industry peers (Freedman, Kearney, and Lederman, 2012; Ball, Macher, and Stern, 2018).[9]

[8] Our evidence is also related to a recent debate on the costs and benefits of "rational ignorance" in the USPTO's patent examination (Lemley, 2001; Frakes and Wasserman, 2019).

[9] Ball, Macher, and Stern (2018) find that a medical device manufacturer's recall news suppresses its innovation but boosts its rivals' innovation. Borisov, Modi, and Ni (2018) find that recall news in the automobile industry may enhance industry-level innovation.

2. Data

Our primary data source is the Food and Drug Administration (FDA) medical device database.[10] The FDA within the Department of Health and Human Services (HHS) is responsible for the oversight of medical devices marketed in the U.S., and the FDA medical device database provides comprehensive information regarding medical devices under FDA control. In the U.S., new medical devices must clear FDA reviews via PMA or 510(k) before being marketed unless exempt by regulation (self-registration).[11] We provide more details of PMA and 510(k) procedures in the Internet Appendix Section A. Not all new medical devices are eligible for 510(k) clearance. The majority of Class 3 devices (for the highest risk) follow the PMA pathway. The majority of Class 2 devices (for the mid-level risk) and a small percentage of Class 1 devices (for the lowest risk) go through 510(k) clearance. The majority of Class 1 devices go to the market with self-registration.

First, we collect the full list of 510(k) devices cleared by the FDA for the period from 2002 to 2021. Using 510(k) device identification numbers (K-numbers) from the list, we download and process each 510(k) premarket notification document from the FDA's website. The 510(k) premarket notification documents contain detailed information including the predicate devices of a 510(k) device. Specifically, we extract the names and identification numbers for predicates as well as the manufacturing firm names, submission and approval dates, and device classes. For some 510(k) premarket notification documents that are not digitalized, we manually collect their information by reading the scanned documents. We provide a detailed discussion of the collection procedure of 510(k) data in the Internet Appendix Section B.

We also standardize all manufacturer names because their names could be misspelled, spelled in a slightly different way, or a subsidiary's name. Later when we consider a sample of public firms, we use these manufacturers' names as matching keys to other databases such as Compustat for firm accounting and financial data. We also collect the information for PMA devices except for their predicate information because PMA devices do not have predicates. These PMA device data are necessary as predicates of a 510(k) device can be PMA devices.

[10] Data source: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

[11] About 67% of medical devices are exempt from the FDA review process as they are in low-risk categories (https://www.gao.gov/assets/gao-09-190.pdf).

Second, we collect the data on medical device recalls also from the FDA's website. It is common in the medical literature to use recalls to reflect the quality of each medical device (Zuckerman, Brown, and Nissen, 2011; Somberg, McEwen, and Molnar, 2014; Rogers, 2023). The recall data are available from 2002 and include a specific link for each event for more detailed recall information. We process the website links electronically and extract further information on recalls such as device identification numbers, recall classes that represent different severity of recall events (class I, II, and III), recall dates, stated reasons for each recall from the firm and the FDA, and manufacturing firm names. The details of our recall data collection procedure are provided in the Internet Appendix Section C. Using the device identification number (K-numbers), we link the recall data to our primary dataset of medical devices. Reasons for recall events are categorized into 44 categories such as device design, process controls, and employee errors. Besides the recall reasons, there are three classes of recalls. Class I recalls are the most serious and substantial recalls, while class III recalls are related to a situation in which the use of or exposure to a violative product is not likely to cause adverse health consequences.

Third, we collect from the FDA Manufacturer and User Facility Device Experience (MAUDE) database the list of medical device reports (MDRs) of suspected medical devices associated with negative public health outcomes such as deaths, injuries, and malfunctions. MDRs can be submitted by mandatory reporters such as manufacturers, importers, and device user facilities and voluntary reporters such as health care professionals, patients, and consumers.[12] It is common in the literature to use such adverse events reported to the FDA as a measure of drug quality (Krieger, Li, and Thakor, 2022; Hsu, Lee, Moon, and Oh, 2024). We link each 510(k) device's MDRs using device identification numbers (K-numbers) to our main dataset.

3. Empirical Design

3.1. Recall rates of 510(k) vs. PMA devices

In Table 1, we compare recall rates of 510(k) vs. PMA devices using the raw FDA medical device database without any additional screening processes. In Panel A, the sample consists of 606,192 device-year observations for 59,146 medical devices cleared by 510(k) and 266,270 device-year observations for 34,098 medical devices approved by PMA. We find that recall rates are

[12] Data source: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

significantly higher for 510(k) devices than PMA devices for all years except 2002. During the aggregate sample period, the 510(k) device recall rate is 10.98% while the PMA device recall rate is 0.98%. The average annual recall likelihood is 1.63% for a 510(k) device and 0.18% for a PMA device. Figure 2 presents a graphical illustration of the recall rates of 510(k) devices vs. PMA devices over time.

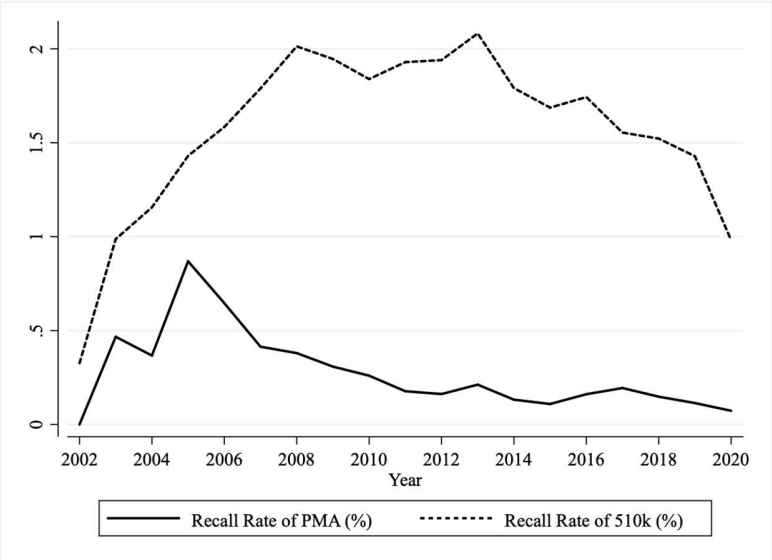


Figure 2. Recall Propensities between 510k and PMA Devices

The figure presents the recall rates of 510(k) vs. PMA devices. The dashed line refers to 510(k) devices, and the solid line refers to PMA devices.

[Insert Table 1 Here]

In Panel B of Table 1, we focus on 510(k) devices only and show that the average recall rates are increasing over the generations of 510(k) devices from a PMA device (ultimate predicate). For these statistics, we trace back to the predicates until we reach a PMA device that does not have any predicates, and this PMA device becomes the 0^{th} generation. The 1^{st} to 3^{rd} generations are all 510(k) devices. The average recall rate of 3^{rd} generation 510(k) devices is as high as 1.68%, whereas the average recall rate of the 1^{st} generation 510(k) devices is 1.30%. This contrast is consistent with our proposition that technical errors from predicates are accumulated and passed down to their follow-on devices through the 510(k) process. Thus, technical errors may intensify through diffusion.

In Panel C of Table 1, we present the time required to develop next-generation devices to further provide insights into the medical device innovation process. On average, it takes a minimum of approximately 3.78 years from the approval of a PMA device to the introduction of its 1st generation 510(k) devices. This duration decreases with subsequent generations, dropping to 2.84 years from the 2nd generation 510(k) devices to the 3rd generation 510(k) devices.

3.2. Sibling Pairs

To draw causal inferences for pass-down errors, we construct sibling pairs of 510(k) devices following the idea of "twin discoveries" of Bikard (2020) and Marx and Hsu (2022). We present our empirical strategy in Figure 3. For every recalled device (P1), we first check if all of its predicates (GP1 and GP2) were not recalled. The predicates (GP1 and GP2) of the recalled device can be either a 510(k) or a PMA device. If any of these predicates had previously been recalled, we exclude the recalled device (P1) from the sample to ensure that P1's recall is not due to technical errors of GP1 or GP2. In the next step, we designate another device (P2) that shares at least one predicate (GP1 in this case) with P1 but has never been recalled; thus, P2 is a sibling device of the recalled device P1. We note that there can be multiple siblings (P2) of one recalled device P1 and that, for one P1, those multiple siblings (P2) can be considered as control devices. This sibling matching provides a unique empirical setting where sibling devices P2 serve as the counterfactuals that come from the same/similar technology base with the recalled device P1. Thus, those technical errors represented by the recall of P1 are rather *exogenous* than inherited because we intentionally choose both P1 and P2 to have only unrecalled predicates. We then collect follow-on devices F1 and F2 as 510(k) devices whose predicates are the recalled device P1 and the unrecalled sibling device P2, respectively.

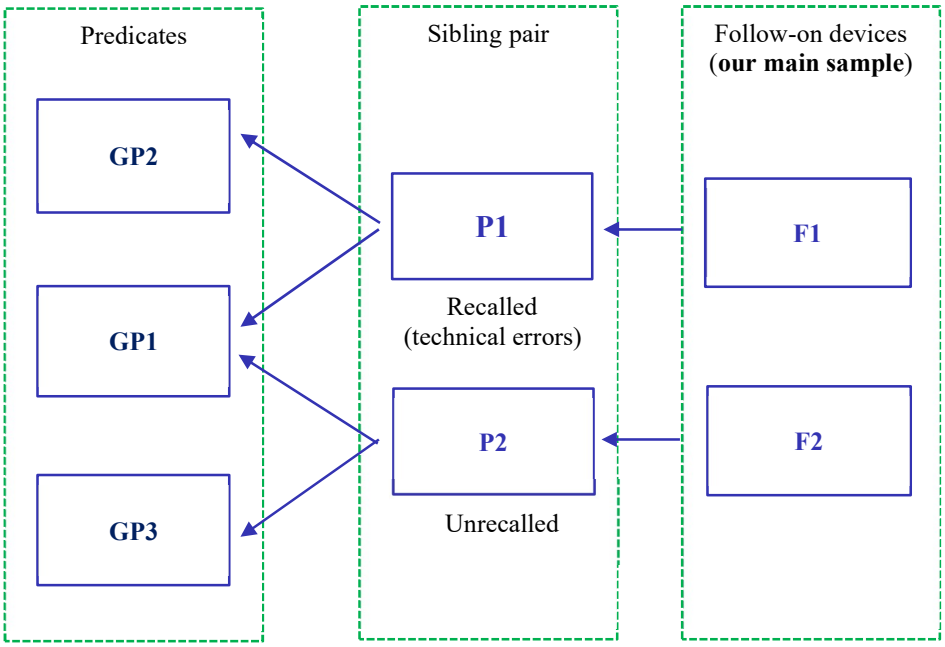


Figure 3. Identification Strategy

F1 and F2 (i.e., follow-on devices) constitute our regression sample. Specifically, we track and compare subsequent recall events (i.e., pass-down errors) of the follow-on devices, F1 and F2, of the recalled device P1 vs. its unrecalled sibling P2. The aforementioned sibling matching procedure results in a sample of 114,601 device-year observations from 12,890 unique 510(k) devices produced by 5,103 unique manufacturers for the sample period from 2002 to 2021. Around 94% of our sample devices are in class 2, which is consistent with the fact that the 510(k) clearance is mainly used for class 2 devices. As an alternative measure for pass-down errors, we also consider adverse events from MAUDE MDRs of F1 and F2. Further, we compare F1 and F2 manufacturers' future growth opportunities, sales growth, subsequent innovation performance and strategies, and likelihood of being a predicate of another device, after the recall event of P1.

Table 2 presents summary statistics of the variables used in our analyses based on our sibling-pair sample. The main variable of our interest is Follow-on Device Recall that is one if the follow-on device is recalled in a given year and zero otherwise. On average, the recall rate of follow-on devices is 1.3% annually and 3.0% when we consider the two subsequent years additionally.

[Insert Table 2 Here]

The average likelihood of those exogenous technical errors at the predicate device level, Predicate Device Recall, is 2.8% from the follow-on devices' perspective. Also, the likelihoods of the recalled predicate being from the same manufacturer and a different manufacturer of its follow-on device are 0.9% and 1.8%, respectively. Among these predicates' recall events, class II recalls are the most common (2.6%) while class I or III recalls are relatively uncommon (0.1% or 0.2%). This is because 510(k) devices, the focus of our paper, are less likely to be related to the highest risk recalls (class I recalls) due to the eligibility requirement of the 510(k) program. Medical devices that are likely to cause serious issues and thus high-risk recall events are usually approved through PMA. Similarly, class III recall events are also less likely to happen to 510(k) devices because medical devices that bear no significant risk are usually exempt from any clearance program including 510(k).

The average number of recalled predicate devices for a follow-on device in a given year is 0.038, and the average fraction of recalled predicate devices to all predicate devices in a given year is 0.014 considering the fact that there can be multiple predicates for a 510(k) device. Medical devices in our sample have been marketed for 5.5 years on average. A medical device manufacturer has on average 39 510(k) devices. In each product code (narrow industry classifications), there are approximately 225 existing 510(k) devices, and about 19 new 510(k) devices are added each year to the product code. Also, a 510(k) device has approximately 2.6 predicate devices within product code. On average, a 510(k) device is cited 0.14 times annually as a predicate of another 510(k) device that is manufactured by a different firm.

4. Results

4.1. Follow-on Device Recalls

We first examine whether a recall event of a follow-on device is associated with the recall of its predicate devices using our sibling-pair sample as specified in the prior section. Specifically, we aim to track the recall possibilities of the follow-on devices of a recalled predicate vs. its unrecalled sibling. This setting is essentially the same as matching a follow-on device-year that experiences its predicate's recall (treated, F1) to another follow-on device-year that does not experience a predicate's recall (control, F2), while predicates of the treated and the control (P1 and P2) share an identical non-recalled predicate device of their own (GP1).

Table 3 shows the results of the test that compares the likelihoods of recall events between those two groups of follow-on devices using a panel of follow-on device-year observations. The dependent variable is an indicator for a recall event of a follow-on device, and the main explanatory variable is whether any of the follow-on device's predicates have been recalled (i.e., Predicate Device Recall). We control for a set of device, manufacturer, and industry characteristics including follow-on device age, the total number of 510(k) devices of the device's manufacturer, the number of all medical devices in the device's product code, the number of new medical devices in the product code, and the average number of predicates for devices in the product code. All these control variables are log-transformed. Our specifications also include year-fixed effects and device-fixed effects. In our robustness checks, we also consider specifications that additionally include sibling-pair fixed effects and find consistent results. Standard errors for statistical inferences are clustered by product code.

[Insert Table 3 Here]

We first consider a linear regression model. In column (1) of Table 3, the dependent variable is the incidence of a follow-on device's recall contemporaneously in the year of its predicate's recall. In column (2), we expand the event window for a follow-on device's recall incidences to cover three years since the predicate recall. We find in the first two columns that follow-on devices' recall events are significantly and positively associated with their predicates' recall events. The coefficient estimates for Predicate Device Recall show that the recall rates of follow-on devices increase by 9.9 percentage points when their predicates are recalled in column (1) and 8.7 percentage points in column (2).[13]

The results are robust to controlling for the product-code by year fixed effects (i.e., industry by year fixed effects) in column (3) which subsume all product-code level control variables or omitted variables. In column (4), we estimate a Poisson regression model instead of a linear regression model as a robustness check. Instead of using an indicator for predicate recalls, we use the number of predicate recalls in column (5) and the ratio of predicate recalls in column (6).[14]

[13] The coefficient for Predicate Device Recall in column (2) can be smaller than in column (1) if a significant portion of recall events for the follow-on devices during the longer event window occurs independently of their predicate devices' recalls.

[14] A follow-on device can have multiple predicates. The ratio of predicate recalls of a follow-on device is the number of its predicates that are recalled divided by the total number of its predicates. For example, if a follow-on device has three predicates, P1, P2, and P3, and only P1 is recalled in a year, the ratio of predicate recalls is 1/3 in that year.

Lastly, in column (7), we consider the full sample instead of the refined sibling-pair sample.[15] Throughout columns (3) to (7), we find that the coefficient estimates for our main variable of interest are positive and significant at the 1% level, and their economic magnitudes are comparable to that in column (1).

In Table IA1 of the Internet Appendix, we present results from the regression specifications with no other control variables and find that our results are robust. Thus, our results are not driven by "bad control" (Heckman and Navarro-Lozano 2004). In Table IA2 of the Internet Appendix, we consider estimating logit regression models instead for columns (1), (2), and (5) to (7) and find that our results are consistent.[16]

To further ensure that sibling pairs (P1 and P2 in Figure 3) come from the same technology base and likely lead to similar follow-on devices (F1 and F2), we construct a better-matched sample. Specifically, we require the sibling-pair devices (P1 and P2) to have at least one follow-on device (F3, not shown in Figure 3) that lists both devices as predicates. This matching ensures that P1 and P2 are technologically similar to a greater extent. After this matching procedure, we exclude F3 from the sample and rerun our regression analyses. We present consistent results in Table IA3 of the Internet Appendix, which further confirms that our results are less likely driven by technological heterogeneity. Despite the fact that this sample provides better matching within sibling pairs, we do not use it in the remaining tests due to concerns about statistical power, as requiring the existence of F3 significantly reduces the sample size.

Given the fact that the 510(k) clearance is mainly used for class 2 devices, we check the robustness of our results by restricting our sample to only class 2 devices. As shown in Table IA4 of the Internet Appendix, we now have 107,928 device-year observations for 12,077 unique class 2 devices cleared by 510(k) (4,773 firms) for the sample period from 2002 to 2021. We find consistent results as in Table 3.

There can be a concern that recall reasons for follow-on devices can be fundamentally different from those for their predicate devices. We address this concern in Table IA5 of the Internet Appendix by focusing on follow-on device recalls that share the same recall cause

[15] The full sample refers to the entire 510(k) device sample without applying the sibling match procedure. The full sample consists of 44,625 510(k) devices (vs. 12,890 510(k) devices in the sibling-pair sample).
[16] It is worth noting that since logit regressions cannot converge with too many fixed effects, we cannot include device fixed effects and product code-year fixed effects in our estimations in Table IA2 of the Internet Appendix.

specified by the FDA as their predicate recalls. Table IA8 presents the results in a format similar to Table 3. We find that the results are similar to those in Table 3 with the coefficient estimates slightly larger across all columns.

4.2. Additional Tests for Passed-down Errors

We extend our analysis by examining how the severity of predicate recalls differentially affects follow-on device recalls in Table IA6 of the Internet Appendix. To do so, we decompose Predicate Device Recall by recall classes I, II, and III which represent the different seriousness levels of recall events. Class I recalls refer to recalls of products that could cause serious injury or death, class II recalls refer to recalls of products that might cause serious injury or temporary illness, and class III recalls refer to recalls of products that are unlikely to cause injury or illness but violate FDA regulations. Class I recalls are thus the most serious recall events. Table IA6 considers the same sample and dependent variables as in columns (1) and (2) of Table 3. Table IA6 shows that the more serious the predicate recalls are, the stronger the relation between predicate recalls and follow-on device recalls is. This finding indicates that follow-on devices of a recalled device are more likely to be recalled when the predicate recall is a class I recall than a class III recall. We find that the magnitudes of the coefficient estimates for Predicate Device Recall are linearly decreasing from recall classes I to III, with the magnitude of the largest effect being 10.3% for class I recalls in column (1).

In Table IA7 of the Internet Appendix, we further examine how the reasons for predicate recalls differentially affect follow-on device recalls. We decompose Predicate Device Recall by whether the FDA-specified recall cause is more likely to be associated with technical errors that can be passed down. There are 43 FDA-specified causes for recall, and we classify them into two groups of high vs. low relevance to technical errors based on the extent to which the specified recall reasons are likely to affect follow-on devices. The high relevance group, denoted as Predicate Device Recall (High Relevance to Technical Errors), includes recall reasons such as component design/selection, device design, process design, and software design. The low relevance group, denoted as Predicate Device Recall (Low Relevance to Technical Errors), includes less fundamental recall reasons such as errors in storage, labelling, counterfeiting, and packaging. Table IA7 shows the results in a similar format as in Table IA6. We find from Table IA7 that predicate recalls being more relevant to technical errors show a stronger relation to follow-

on device recalls with statistical significance. This finding corroborates the existence of diffused errors through the 510(k) program.

In Table IA8 of the Internet Appendix, we examine the effect of time spent on developing next-generation devices. We hypothesize that follow-on devices developed within a shorter duration from the approval of their predicate devices are more susceptible to inherited technical errors. To test for this prediction, we classify follow-on devices into two groups based on whether they have shorter vs. longer development times relative to their predicates.[17] Table IA8 presents the results in a format similar to Table IA6. Our findings indicate that predicate recalls have a more significant impact on the recall likelihood of follow-on devices developed in a shorter time compared to those taking longer to develop. This result is consistent with the interpretation that technical errors are more likely to be passed down to follow-on devices developed relatively quickly, as there is insufficient time to identify potential problems in the predicate devices.

4.3. Alternative Explanations: Device Heterogeneity and Manufacturer Quality

We carefully developed our empirical design using a sibling pair of devices where both devices come from the same technology base (i.e., the same predicates) but only one of the two (i.e., the recalled device) carries technical errors. Yet, there can be still alternative explanations for our findings.

4.3.1. Device Heterogeneity

An underlying assumption of our construction of sibling pairs of predicates is that both follow-on devices are similar except for the random error in the treated predicate (P1). However, there is a concern that the sibling devices of the pairs are fundamentally different in terms of technology complexity, although they come from the same predicates. This complexity concern can be particularly substantiated if there exist non-shared predicates (GP2 and GP3 in Figure 3) that may influence the complexity of follow-on devices. For example, if there are many more predicates for the treated predicate (P1) relative to the untreated predicate (P2), the follow-on devices of the treated predicate could have more recall events due to the complex nature of the devices. We note

[17] The development duration is the shortest interval between the approval year of the follow-on device and the approval years of its predicate devices.

that this concern has been mitigated by device-fixed effects that can control for device complexity in our regression specifications. Nonetheless, we further restrict the sample to the sibling pairs that have only a single predicate (i.e., GP1 is the only predicate for both P1 and P2 in Figure 3) and their follow-on devices that also have a single predicate (i.e., P1 and P2 are the only predicates for F1 and F2, respectively, in Figure 3). Even with this strictly refined sample, we find robust results in Table IA9 of the Internet Appendix. In addition, to make sure the entire sibling pair heterogeneity, including device complexity, does not drive our results, we include sibling-pair fixed effects in the regression models in Table 3. Consistent results with these sibling-pair fixed effects are presented in Table IA10 of the Internet Appendix.

As discussed earlier, Table IA3 of the Internet Appendix is based on a sample in which we require the sibling-pair devices (P1 and P2 in Figure 3) to have at least one follow-on device (F3, not shown in Figure 3) that cites both devices. This matching ensures that P1 and P2 are technologically similar, as both are listed as predicates by F3. We find consistent results, which suggests that our findings are not driven by an alternative explanation based on device heterogeneity.

4.3.2. Manufacturer Quality

We acknowledge that the reason for the technical error only in the treated predicate (P1) might not be completely random. Such non-random reasons include the quality of manufacturing firms. If the recalled predicate (P1) was made by a low-quality manufacturing firm and the same firm produced a large number of the follow-on devices as well, the higher recall rates we observe in the follow-on devices of recalled predicates would be from the low quality of manufacturers, not from the pass-down errors. We first note that 70.56% of follow-on devices are produced by different manufacturers; thus, our results cannot be completely driven by some low-quality manufacturers. In addition, we include device fixed effects in all our regressions, which offer a higher granularity level than manufacturer fixed effects and thus can mitigate this concern.

Nevertheless, we directly address this alternative explanation by including manufacturers' time-varying recall rates as an additional control variable in our regressions. Specifically, we calculate the previous three-year average of the fraction of the manufacturer's 510(k) devices that are recalled out of the total number of the manufacturer's 510(k) devices. Table IA11 of the Internet

Appendix presents the results. We find that our results remain intact with the inclusion of the additional control variable that proxies the quality of manufacturers. Interestingly, the coefficient estimates for the quality of manufacturers in the past three years are significantly negative, indicating that a manufacturer's previous recall rate is less likely to predict the recall of its new devices. A possible reason for such a negative relation is that the problematic devices produced by low-quality manufacturers may have been excluded from the market due to their previous recalls, thereby reducing their contribution to future recall likelihood.

4.4. Heterogeneous Treatment Effects: Pass-down Technical Errors vs. Precautionary Recalls

Another alternative explanation is precautionary recalls by the manufacturers who produce a device that cites the recalled predicate. Such precautionary recalls aim to ease customer concerns, not to address fundamental technical issues. Digging deeper, in Table 4, we examine whether the increase in follow-on device recall rates with their predicate recalls is attributable to pass-down technical errors or the alternative explanation based on precautionary recalls. Specifically, we consider two separate recall cases where both follow-on and predicate devices are produced by the same manufacturer and by different manufacturers in columns (1) and (3). We further divide the recall cases of different manufacturers based on the technological proximity between predicate manufacturers and follow-on device manufacturers into two groups, High vs. Low technological proximity, in columns (2) and (4). Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices. Our assumption underlying these analyses is that a technology and its errors are more easily diffused within a firm rather than across firms and also across firms with high technological proximity rather than with low technological proximity. While the increase in follow-on device recalls after predicate recalls could reflect both diffused errors and precautionary firm reactions due to negative customer sentiment at the same time, the different patterns based on (i) the same manufacturers vs. different manufacturers and (ii) firms with high technological proximity vs. low technological proximity for different manufacturers should be more attributable to diffused errors.

In Table 4, we use the same set of dependent variables as in columns (1) and (2) of Table 3. The key independent variables in columns (1) and (3) are (i) Predicate Device Recall by Same Manufacturer that is one if any predicate device of the follow-on device produced by the same

manufacturer is recalled in a given year and zero otherwise, and (ii) Predicate Device Recall by Diff. Manufacturer that is one if the recalled predicate device is not produced by the follow-on device's manufacturer in a given year and zero otherwise. In columns (2) and (4), Predicate Device Recall by Diff. Manufacturer is replaced with Predicate Device Recall by Diff. Manufacturer – High Tech. Proximity and Predicate Device Recall by Diff. Manufacturer – Low Tech. Proximity. Different manufacturers are considered to be high (low) technology proximate if the cosine similarity of the CPC vectors of their patent stocks is higher (lower) than the sample median.

[Insert Table 4 Here]

We find that the recall likelihood of follow-on devices increases with predicates' recalls in both same vs. different manufacturer cases but the extents are significantly different. Predicate recalls by the same manufacturing firms have an approximately three times stronger effect on the likelihood of follow-on device recalls. In columns (1) and (3), the magnitudes of the coefficients are 19.1% and 17.3% for the same-manufacturer cases and 5.9% and 5.3% for the different-manufacturer cases. The stronger effect on the follow-on device recall for the same-manufacturer cases supports the existence of the mechanism of diffused errors because a new device is more likely to inherit technology and know-how from its predicate when they are both produced by the same manufacturer.

The tests in columns (2) and (4) allow us to compare the effect of predicate recalls on the recall likelihood of follow-on devices between different manufacturer cases of high vs. low technological proximity. These tests especially strengthen the interpretation of results based on diffused errors. The coefficient estimates of Predicate Device Recall by Diff. Manufacturer – High Tech. Proximity are larger than those of Predicate Device Recall by Diff. Manufacturer – Low Tech. Proximity in both columns, although the differences are not statistically significant. The closer the predicate manufacturer and its follow-on device manufacturer are in their technology spaces, the more likely the follow-on device inherits the predicate device's errors. Thus, our findings in columns (2) and (4) further support our proposition that technical errors of predicate devices pass down to their follow-on devices. Nevertheless, we cannot completely rule out the possibility of precautionary recalls related to customer sentiment yet in these analyses because firms may recall their products just to restore customers' confidence and to maintain brand image regardless of technical issues.

4.5. Alternative Quality Measure: Adverse Events

We additionally examine how predicate recalls are associated with follow-on devices' adverse events from the MAUDE MDRs in Table 5. Adverse events of medical devices also capture the effect of potential pass-down errors from predicates and can be an alternative measure to recall events. Different from considering follow-on devices' recall events in a given year after predicate recalls in earlier tests, we focus on adverse events from each device's approval till (i.e., before) the predicate recalls because the follow-on devices may sell less, be recalled, or be fixed in response to their predicate recalls. Our assumption is that even before a predicate recall is known, the technical issues that cause the recall later already exist in the predicate device and thus would have passed down to follow-on devices and revealed in their own adverse events. Specifically, the dependent variables in Table 5 are the average number of annual adverse event reports in columns (1) to (3) and the average number of annual *serious* adverse event reports in columns (4) to (6), for a follow-on device from its approval year until its predicate device's recall year. Serious adverse event reports refer to cases in which the patient outcome is one of the serious conditions (death or injury). Thus, we are estimating a cross-sectional regression, and there is one observation per follow-on device in the sample. For a control follow-on device in our sibling-pair sample whose predicate is not recalled, we consider the average number of annual adverse event reports or annual serious adverse event reports during the first three years since its approval.[18]

[Insert Table 5 Here]

In Table 5, we find that a follow-on device is more likely to receive adverse event reports and serious adverse event reports when its predicate is recalled as shown in columns (1) and (4). Consistent with our previous results in Table 4, we also find in columns (2) and (5) that the effect is larger when the recalled predicate is manufactured by the same manufacturer vs. a different manufacturer, which further supports the error diffusion mechanism. In columns (3) and (6), we also show that the effect of the predicate recall from a different manufacturer is more concentrated on the case where the technological proximity between predicate and follow-on device manufacturers is high. The coefficient estimates for Predicate Device Recall by Diff. Manufacturer – Low Tech. Proximity are statistically insignificant, which is consistent with the interpretation

[18] Our results are robust to using an alternative time period to measure adverse events for control devices, such as the period from each control device's approval to its treated pair's predicate recall.

that the increase in follow-on devices' adverse events is particularly related to pass-down technical errors from the predicate manufacturer to the follow-on device manufacturer rather than the negative customer sentiment leading to precautionary recalls.

Overall, the results in Tables 4 and 5 collectively support the mechanism of the pass-down technical errors. It appears that the 510(k) program, which only requires the new device to be substantially equivalent to another previously marketed device, creates an issue where undetected technical errors in a particular technology may pass down through spillovers and then accumulate into more substantial ones.

4.6. Device Portfolio

Next, we examine how medical device manafacturers' innovation strategies are influenced by predicate recalls. We first consider the number of new 510(k) devices launched in the next year for a firm as a measure of the firm's invention intensity. It is possible that firms may reduce overall investment in new inventions following recalls of their devices' predicates. As in the previous analyses, we examine the overall effect and then compare the number of new 510(k) device launches between firms that produce vs. only cite the recalled predicates of their own 510(k) devices (i.e., the same-manufacturer vs. different-manufacturer cases, respectively). We also further differentiate firms with high vs. low technological proximity to the predicate device manufacturers for the different manufacturer case. We present the results in Table 6 using a firm-year panel for all medical device manufacturers from 2002 to 2021.

[Insert Table 6 Here]

In columns (1) to (3), the dependent variable is Log (1+New 510k Device at T_{+1}). The overall effect of predicate recalls on subsequent inventions is statistically insignificant in column (1), which means that predicate device recalls do not reduce subsequent 510(k) inventions. When we separately consider recalls by the same vs. different manufacturers in column (2) and by those with high vs. low technological proximity to predicate manufacturers in column (3), we still find that predicate recall do not affect the level of investments in overall subsequent inventions.

Given that firms do not reduce their overall investments in new inventions, it is also likely that they might shift their focus away from troubled areas to new ones. We test this hypothesis regarding firm pivoting strategies in columns (4) to (6). Specifically, we consider how firms

choose industries (product codes) in the 510(k) market using Product Code Diversification at T_{+1} (Inv. HHI), which is the inverse of the Herfindahl-Hirschman Index (HHI) of the product portfolio across different product codes measured one year after the predicate device recall. While the overall effect of predicate recalls is insignificant in column (4), the opposite effects emerge when we separately consider recalls by the same vs. different manufacturers in column (5). We find that firms are more likely to maintain their device portfolios across more diversified industries after their own predicate devices are recalled. We do not find such pivoting strategies for the firms that experience recalls of predicate devices from different manufacturers. The faded market concentration suggests these firms adopt less exploitative innovation strategies after experiencing recalls from their own device portfolios. These results also show the stark differences between the concerns about pass-down technical errors and the increased market opportunities for firms that produce vs. only cite the recalled predicates (i.e., the same-manufacturer vs. different-manufacturer cases, respectively).

In column (6), we also find that among different manufacturers, the pivoting effect exists in those with high technological proximity to their predicate manufacturers whereas market concentration relatively becomes stronger for those with low technological proximity. These results support the idea that there can be market opportunities for manufacturers that are independent and technologically distant.

5. Analyses of Consequences

In this section, we further explore the consequences of predicate recalls on follow-on devices. We assess both the impact of these follow-on devices and the financial performance of their manufacturers.

5.1. Citations after Predicate Recalls

For the impact of predicate recalls on follow-on devices, we consider whether predicate recall events affect subsequent citations of a follow-on device. A citation of a device in our study refers to the occasion when the device is cited as a predicate of subsequent 510(k) devices (Everhart, 2021). To address the self-citation concern by the same manufacturer, we only consider citations from devices produced by *other* manufacturers. By doing so, our citation measure reflects the impact of the follow-on device and enables us to measure how predicate recalls influence the follow-on devices' impact on subsequent inventions. The intuition is that when other

manufacturers become aware of news about recalls of a device's predicates, they may become concerned about potential technical errors in the device and as a result, they may be less likely to benchmark the device for future inventions. The results on subsequent citations are presented in Table 7.

[Insert Table 7 Here]

The dependent variable in columns (1) to (3) is Log(1+Number of Citations by Other Manufacturers at T_{+1}) which is measured in the year after the follow-on device's predicate is recalled. The dependent variable in columns (4) to (6) is Log(1+Number of Citations by Other Manufacturers in $T_{[+1,+3]}$) which is measured for three years after the follow-on device's predicate is recalled. The results in columns (1) and (4) show that the number of citations by subsequent devices of other manufacturers in the following year after the predicate recall does not significantly change but significantly increases when the citations for the next three years after the predicate recall are considered.

When we separately consider recalls by the same vs. different manufacturers of the follow-on device and its predicates in columns (2) and (5), we find the opposite effects. Predicate device recalls significantly decrease citations of follow-on devices for the same manufacturers but significantly increase citations of follow-on devices for different manufacturers. For example, the economic magnitudes of the effects in column (2) are a 2% decrease and a 2.2% increase in the number of subsequent citations for the same manufacturers and different manufacturers, respectively. Further, the positive effect on citations for the different-manufacturer case is concentrated only on predicate device recalls by technologically distant manufacturers as in columns (3) and (6).

These results further support that the pass-down technical errors within the same manufacturer are the main reason for the reduced impact of a follow-on device. If the number of citations of the follow-on device that has a recalled predicate produced by a different manufacturer also significantly decreased, it would indicate that negative customer sentiment over recalled predicates plays a role. Our results in Table 8, therefore, show that medical device manufacturers are more responsive to potential pass-down technical errors than customer sentiment on recalled products. Overall, our findings on subsequent inventions after predicate recalls shed light on the

materiality of diffused errors in technology and how medical device manufacturers adversely affected by technology spillovers respond to them.

5.2. Financial Performance after Predicate Recalls

We further investigate the financial performance of manufacturers of follow-on devices after their predicate recalls. The sample for this analysis is limited to U.S. public firms due to the availability of financial and accounting data for medical device manufacturers. To use the Compustat database, we match firm names in our list of medical device manufacturers to firm names in Compustat. The final matched data have 5,491 unique public manufacturers. It is noteworthy that our analysis is at the firm level and thus we do not restrict our sample to the sibling-pair sample. We examine whether predicate recall events are associated with a decrease in the financial performance of the follow-on device manufacturers. Specifically, we consider Tobin's q and sales growth of those firms during the three years after the predicate recalls. We present the results in Table 8 using a firm-year panel for public medical device manufacturers from 2002 to 2021.

[Insert Table 8 Here]

We first find in columns (1) and (4) that the overall effects of predicate recall events on the financial performance of follow-on devices are insignificant. However, when we compare the cases between the same vs. different manufacturers, the opposite effects emerge. In columns (2) and (5), when the predicate recall by the same firm is considered, we find that both Tobin's q and sales growth of the firm significantly decrease. The economic magnitudes of the effects are a 4.5% decrease in Tobin's q from its unconditional mean and a 17.35% decrease in sales growth from its unconditional mean.[19] These significant negative outcomes in financial performance come from the effects of the recall events on the firms that experience recalls (the direct recall effect) and also from the negative spillovers effects of the recalled predicates on the follow-on devices produced by the same firms (the pass-down error effect). We are unable to disentangle the two components in this analysis as the same manufacturers produce recalled predicate devices and their follow-on devices.

On the other hand, when the predicate recall is by a different firm, we find a *positive* and significant effect on the subsequent Tobin's q and sales growth in columns (2) and (5). These

[19] The sample means of Tobin's q and sales growth are 2.404 and 0.098, respectively.

results are important to differentiate the customer sentiment effect from the pass-down error effect. It appears that financial markets favor firms with 510(k) devices if their predicates produced by a different firm are recalled. This is inconsistent with the interpretation of the customer sentiment effect, for which we expect that even the predicate recalls from different manufacturers impact a firm's market value or sales negatively. Furthermore, the significant increase in sales growth when the recalled predicate is not from the follow-on device's manufacturer implies the substitution effect towards devices with smaller concerns about pass-down technical errors.

Also, this substitution effect is further supported by the results in columns (3) and (6) as we find that the positive effect of predicate recall on different manufacturing firms only concentrates on the group of low technological proximity to the predicate device manufacturers. The effect of predicate recall on different manufacturing firms with high technological proximity is statistically insignificant and close to zero. Given the existence of such a substitution effect, follow-on device manufacturers that are technologically distant from recalled predicate manufacturers are less likely to announce precautionary recalls.

6. Conclusions

The diffusions of technical errors and flaws are unavoidable side effects of technology spillovers. Given the dominating role of cumulative research and technology spillovers in modern innovation and economic growth, such diffused errors may develop into a severe issue for both firms and societies and thus deserve further investigation. In this paper, we focus on the medical device industry, which is important for public health but is also more subject to diffused errors under the 510(k) premarket notification program.

We exploit the predicate list in the 510(k) program in which a new device is claimed to be substantially equivalent to existing ones (i.e., predicates) to measure technology spillovers and transfers. With the predicate lists, we design a sibling-pair sample to draw a causal interpretation of the effects of diffused errors. For each recalled 510(k) device, we find its sibling that shares the same technology root but has never been recalled. Thus, the recalled device reflects technical errors that are rather exogenous than inherited. We then track the recalls of the follow-on devices of this sibling pair. In our regression analyses focusing on the follow-on devices of sibling pairs, we find that the follow-on devices of a recalled predicate are more likely to be recalled or to receive adverse

event reports than those of the unrecalled sibling of the recalled predicate. Such a pattern is more pronounced when (i) the recall is related to more serious health concerns, (ii) the recall is more related to technical issues, and (iii) the recall is more attributable to diffused errors.

When we examine the relation between predicate recalls and follow-on device manufacturers' product launches, device portfolio diversification, and financial performance, we find supportive evidence for a substitution effect: when a follow-on device manufacturer is more distant from the manufacturers of recalled predicates in the technology domain, it receives more forward citations from subsequent devices and exhibits higher Tobin's q and sales growth. These novel results add to the industrial organization literature by providing new perspectives on how competitors capture the potentially lost market share of firms with flawed products and how markets react to such product market opportunities.

Our empirical evidence further provides new insights into the regulation of medical devices. While 510(k) is a cost-effective review channel compared to PMA, by not directly examining the device's safety and effectiveness, it may diffuse and intensify technical errors over the generations of 510(k) medical devices. More broadly, our study offers a caution against many recent targeted expedited programs by the FDA such as Priority Review, Accelerated Approval, Fast Track, and Breakthrough Therapy Designation that facilitate faster delivery of a product but may compromise on quality. Further investigations are certainly called for to reach balanced or optimal policies.

Appendix A. Variable Definitions

Follow-on Device Recall at T_0	An indicator that is one if a follow-on device is recalled in a given year and zero otherwise.
Follow-on Device Recall at $T_{[0,+2]}$	An indicator that is one if a follow-on device is recalled from the event year of predicate recall to two years after the event year of predicate recall and zero otherwise.
Predicate Device Recall	An indicator that is one if the follow-on device's predicate device is recalled in a given year and zero otherwise.
Predicate Device Recall by Diff. Manufacturer	An indicator that is one if the follow-on device's predicate, produced by a different manufacturer, is recalled in a given year and zero otherwise.
Predicate Device Recall by Diff. Manufacturer – High (Low) Tech. Proximity	An indicator that is one if technological proximity between predicate and follow-on device manufacturers is high (low) when predicate and follow-on devices are manufactured by different firms and zero otherwise. Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices.
Predicate Device Recall by Same Manufacturer	An indicator that is one if the follow-on device's predicate, produced by the same manufacturer, is recalled in a given year and zero otherwise.
Predicate Device Recall Class I/II/III	An indicator that is one if the follow-on device's predicate is recalled in a given year by the recall class I/II/III and zero otherwise. (e.g., Class I: Recalls for products which could cause serious injury or death; Class II: Recalls for products which might cause serious injury or temporary illness; Class III: Recalls for products which are unlikely to cause injury or illness, but violate FDA regulations.)
Number of Predicate Device Recalls	The total number of a follow-on device's predicates that are recalled in a given year.
Ratio of Predicate Device Recall	The ratio of recalled predicate devices in a given year to all predicate devices of a follow-on device.
Age	The difference between the given year and the FDA clearance year of the 510(k) medical device.
Log(1+Number 510K Devices by Firm)	The log of one plus the total number of 510(k) devices for a firm in a given year.
Log(1+Number of Devices in Product Code)	The log of one plus the total number of 510(k) devices in each product code in a given year.
Log(1+Number of New Devices in Product Code)	The log of one plus the total number of newly cleared 510(k) devices in each product code in a given year.
Log(1+Average Number of Predicates by Product Code)	The log of one plus the average number of predicate devices among 510(k) devices in each product code in a given year.
Number of Citations by Other Manufacturers at T_{+1}	The total number of newly cleared 510(k) devices that cite the follow-on device as a predicate device during one year after the event year of the follow-on device's predicate recall.
Number of Citations by Other Manufacturers at $T_{[+1,+3]}$	The total number of newly cleared 510(k) devices that cite the follow-on device as a predicate device during three years after the event year of the follow-on device's predicate recall.
Number of New 510k Device at T_{+1}	The number of newly cleared 510(k) devices during one year after the event year of the follow-on device's predicate recall.
Product Code Diversification at T_{+1} (Inv. HHI)	The inverse of the Herfindahl-Hirschman Index (HHI) of the product portfolio across different product codes measured one year after the predicate recall.
Recall Ratio of Firm in Prev 3yrs	The previous three-year average of manufacturer's 510(k) devices that are recalled out of the total number of the manufacturer's 510(k) devices.
Tobin's q at T_{+1}	A follow-on device manufacturer's *Tobin's q* in one year after the event year of predicate recall.
Sales Growth at T_{+1}	A follow-on device manufacturer's sales growth in one year after the event year of predicate recall.

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Table 1. Recall Propensities and Invention Time of 510(k) and PMA Devices

This table compares the average recall rates of medical devices reviewed through the 510(k) premarket notification (510(k)) and the premarket approval (PMA). In Panel A, the sample consists of 606,192 device-year observations for 59,146 medical devices cleared by 510(k) and 266,270 device-year observations for 34,098 medical devices approved by PMA. In Panel B, we trace a 510(k) device's predicate trajectory until we reach a PMA device that does not have any predicates. This PMA ancestor device becomes the 0^{th} generation. The 1^{st} to 3^{rd} generations are all 510(k) devices. In Panel C, we present the average time to develop subsequent-generation 510(k) devices. Years Taken is the minimum difference between the approval year of a new device and the approval year of its predicate device.

Panel A. Average Recall Rates (%) by Year

Period	510(k)	PMA	Difference	t-stat
2002-2020 Total	10.976	0.977	10.000***	57.45
Observations	59,146	34,098		
2002-2020 Annual	1.631	0.178	1.454***	57.83
Observations	606,192	266,270		
2002	0.326	0.000	0.326	1.46
2003	0.987	0.467	0.520*	1.81
2004	1.156	0.367	0.788***	3.13
2005	1.430	0.869	0.561**	2.30
2006	1.584	0.646	0.938***	4.39
2007	1.789	0.414	1.375***	7.01
2008	2.013	0.380	1.633***	9.01
2009	1.946	0.308	1.638***	10.23
2010	1.839	0.260	1.580***	11.27
2011	1.929	0.177	1.752***	13.62
2012	1.940	0.162	1.778***	15.12
2013	2.082	0.212	1.871***	16.48
2014	1.791	0.132	1.659***	16.95
2015	1.687	0.109	1.578***	17.54
2016	1.743	0.161	1.583***	18.18
2017	1.554	0.194	1.360***	17.27
2018	1.522	0.148	1.374***	18.64
2019	1.428	0.114	1.314***	19.27
2020	0.981	0.073	0.907***	16.64
Observations	606,192	266,270		

Panel B. Average Recall Rates (%) by Generation

510(k) Generation	Average Recall Rates (%)	Std. Dev	Min	Median	Max	Obs.
1st	1.301	11.337	0.000	0.000	100.000	1,076
2nd	1.909	13.689	0.000	0.000	100.000	1,362
3rd	1.678	12.852	0.000	0.000	100.000	1,132

Panel C. Time to Invent New Generation

510(k) Generation	Years Taken	Std. Dev	Min	Median	Max	Obs.
1st	3.779	4.027	0.000	3.000	29.000	1,076
2nd	3.026	2.931	0.000	2.000	29.000	1,362
3rd	2.839	2.596	0.000	2.000	18.000	1,132

Table 2. Summary Statistics for the Sibling-Pair Sample

This table presents summary statistics for the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall and the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices approved by the 510(k) program (5,103 firms) for the sample period from 2002 to 2021. *Follow-on Device Recall* is an indicator that is one if a follow-on device is recalled in a given year and zero otherwise. *Predicate Device Recall* is an indicator that is one if the follow-on device's predicate device is recalled in a given year and zero otherwise. Appendix A provides detailed variable descriptions.

	Mean	Std. Dev	25th	50th	75th	Obs.
Follow-on Device Recall at T_0	0.013	0.112	0.000	0.000	0.000	114,601
Follow-on Device Recall at $T_{[0,+2]}$	0.030	0.172	0.000	0.000	0.000	114,601
Predicate Device Recall	0.028	0.164	0.000	0.000	0.000	114,601
Predicate Device Recall by Same Manufacturer	0.009	0.094	0.000	0.000	0.000	114,601
Predicate Device Recall by Diff. Manufacturer	0.018	0.133	0.000	0.000	0.000	114,601
Predicate Device Recall by Diff. Manufacturer - High Tech. Proximity	0.003	0.051	0.000	0.000	0.000	114,601
Predicate Device Recall by Diff. Manufacturer - Low Tech. Proximity	0.004	0.059	0.000	0.000	0.000	114,601
Predicate Device Recall Class I	0.001	0.031	0.000	0.000	0.000	114,601
Predicate Device Recall Class II	0.026	0.158	0.000	0.000	0.000	114,601
Predicate Device Recall Class III	0.002	0.042	0.000	0.000	0.000	114,601
Number of Predicate Device Recalls	0.038	0.290	0.000	0.000	0.000	114,601
Ratio of Predicate Device Recall	0.014	0.097	0.000	0.000	0.000	114,601
Age	5.498	4.349	2.000	5.000	8.000	114,601
Log(1+Age)	1.592	0.817	1.099	1.792	2.197	114,601
Number 510K Devices by Firm	38.645	69.759	3.000	11.000	39.000	114,601
Log(1+Number 510K Devices by Firm)	2.667	1.401	1.386	2.485	3.689	114,601
Number of Devices in Product Code	225.018	260.592	47.000	129.000	293.000	114,601
Log(1+Number of Devices in Product Code)	4.755	1.265	3.871	4.868	5.684	114,601
Number of New Devices in Product Code	18.787	20.945	4.000	11.000	26.000	114,601
Log(1+Number of New Devices in Product Code)	2.456	1.062	1.609	2.485	3.296	114,601
Average Number of Predicates by Product Code	2.611	1.502	1.750	2.261	3.111	114,601
Log(1+Average Number of Predicates by Product Code)	1.224	0.332	1.012	1.182	1.414	114,601
Number of Citations by Other Manufacturers at T_{+1}	0.139	0.464	0.000	0.000	0.000	105,817
Log(1+Number of Citations by Other Manufacturers at T_{+1})	0.086	0.259	0.000	0.000	0.000	105,817
Number of Citations by Other Manufacturers at $T_{[+1,+3]}$	0.279	0.634	0.000	0.000	0.000	105,817
Log(1+Number of Citations by Other Manufacturers at $T_{[+1,+3]}$)	0.170	0.348	0.000	0.000	0.000	105,817
Number of New 510k Device at T_{+1}	0.335	1.329	0.000	0.000	0.000	109,875
Log(1+Number of New 510k Device at T_{+1})	0.148	0.381	0.000	0.000	0.000	109,875
Product Code Diversification at T_{+1} (Inv. HHI)	0.268	0.319	0.000	0.000	0.500	109,875
Average Number of MAUDE Reports	0.425	0.439	0.000	0.288	0.847	1,886
Log(1+Average Number of MAUDE Reports)	3.235	17.720	0.000	0.333	1.333	1,886
Average Number of Serious MAUDE Reports	0.381	0.395	0.000	0.288	0.847	1,885
Log(1+Average Number of Serious MAUDE Reports)	0.588	0.668	0.000	0.333	1.333	1,885

Table 3. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample

This table reports results from the regressions of follow-on device recall on predicate device recall. In columns (1)-(6), we use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In column (7), we use the full sample (before sibling matching) that consists of 400,441 device-year observations for 44,625 medical devices cleared by 510(k). In all columns except for column (4), the linear probability model regression is used. The dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall except for columns (2), (5), and (6). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we regress *Follow-on Device Recall at* T_0 on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*) as the main independent variable. In column (7), we reestimate the regression in column (1) using the full sample. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall						
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls	Full Sample
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Predicate Device Recall	0.099***	0.087***	0.083***	1.612***			0.103***
	(0.011)	(0.010)	(0.010)	(0.110)			(0.007)
Number of Predicate Device Recalls					0.061***		
					(0.004)		
Ratio of Predicate Device Recall						0.185***	
						(0.022)	
Log(1+Age)	0.008***	-0.001	0.007***	0.753***	0.007***	0.009***	0.010***
	(0.002)	(0.003)	(0.002)	(0.144)	(0.002)	(0.002)	(0.001)
Log(1+Number 510K Devices by Firm)	-0.004*	-0.011**	-0.005*	-0.122	-0.004*	-0.004*	-0.007***
	(0.002)	(0.005)	(0.003)	(0.156)	(0.002)	(0.002)	(0.002)
Log(1+Number of Devices in Product Code)	-0.007*	-0.017**		-0.388	-0.006*	-0.007*	-0.003
	(0.003)	(0.008)		(0.251)	(0.003)	(0.003)	(0.002)
Log(1+Number of New Devices in Product Code)	-0.002	-0.006**		0.020	-0.001	-0.002	-0.001
	(0.001)	(0.003)		(0.086)	(0.001)	(0.001)	(0.001)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.002		-0.092	-0.001	-0.001	-0.000
	(0.002)	(0.003)		(0.127)	(0.002)	(0.002)	(0.001)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No	No
Observations	114,601	114,601	112,741	10,669	114,601	114,601	400,441
Adjusted R-squared	0.105	0.253	0.079	0.136	0.060	0.062	0.101

Table 4. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Technological Proximity

This table reports results from the linear probability model regressions of follow-on device recall on predicate recall. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In columns (1) and (2), the dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall. In columns (3) and (4), the dependent variable is *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on device is recalled during the three years since the predicate device recall and zero otherwise. *Predicate Device Recall by Same Manufacturer* is one if the follow-on device's predicate produced by the same manufacturer is recalled in a given year and zero otherwise. *Predicate Device Recall by Diff. Manufacturer* is one if the follow-on device's predicate produced by a different manufacturer is recalled in a given year and zero otherwise. We decompose *Predicate Device Recall by Diff. Manufacturer* into high vs. low technological proximity. Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall			
	Follow-on Device Recall at T_0		Follow-on Device Recall at $T_{[0-+2]}$	
Independent Variable	(1)	(2)	(3)	(4)
Predicate Device Recall by Same Manufacturer: (a)	0.191***	0.190***	0.173***	0.172***
	(0.021)	(0.021)	(0.020)	(0.019)
Predicate Device Recall by Diff. Manufacturer: (b)	0.059***		0.053***	
	(0.010)		(0.010)	
Predicate Device Recall by Diff. Manufacturer		0.109***		0.093***
- High Tech. Proximity: (c)		(0.033)		(0.023)
Predicate Device Recall by Diff. Manufacturer		0.069***		0.080***
- Low Tech. Proximity: (d)		(0.022)		(0.028)
Log(1+Age)	0.008***	0.008***	-0.000	-0.000
	(0.002)	(0.002)	(0.003)	(0.003)
Log(1+Number 510K Devices by Firm)	-0.004**	-0.004**	-0.011**	-0.010**
	(0.002)	(0.002)	(0.005)	(0.005)
Log(1+Number of Devices in Product Code)	-0.006*	-0.006*	-0.017**	-0.017**
	(0.003)	(0.003)	(0.007)	(0.007)
Log(1+Number of New Devices in Product Code)	-0.002	-0.002	-0.006**	-0.006**
	(0.001)	(0.001)	(0.003)	(0.003)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.001	-0.002	-0.002
	(0.002)	(0.002)	(0.003)	(0.003)
Year Fixed Effects	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes
Observations	114,601	114,601	114,601	114,601
Adjusted R-squared	0.114	0.113	0.294	0.294
p-value for the difference (a) and (b)	0.000***		0.000***	
p-value for the difference (c) and (d)		0.145		0.664

Table 5. Predicate Device Recall and Adverse Events of Follow-on Devices

This table reports results from the cross-sectional, device-level OLS regressions in which the dependent variable is the average number of adverse event reports from the Manufacturer and User Facility Device Experience (MAUDE) database for the period between a device's approval and its predicate device recall. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 1,886 devices (one observation per device) with 249 predicate device recall events from 2002 to 2021. For treatment devices, we measure the average annual number of adverse event reports from its approval year to its predicate device recall year. For control devices, we measure the average annual number of adverse event reports during the first three years since its approval year. In columns (1) to (3), we count all adverse event reports, and in columns (4) to (6), we count serious adverse event reports in which the patient outcome is one of the serious conditions (death or injury). Both of the dependent variables are log-transformed. In columns (1) and (4), the key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In columns (2) and (5), the key independent variable is *Predicate Device Recall by Same (Diff.) Manufacturer* that is one if the follow-on device's predicate produced by the same (a different) manufacturer is recalled in a given year and zero otherwise. In columns (3) and (6), we decompose *Predicate Device Recall by Diff. Manufacturer* into high vs. low technological proximity. Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices. In all columns, we control for approval year fixed effects and product code fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ∗∗∗, ∗∗, and ∗ indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Log(1+Average Number of MAUDE Reports)			Log(1+Average Number of Serious MAUDE Reports)		
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.227***			0.145***		
	(0.029)			(0.033)		
Predicate Device Recall by Same Manufacturer: (a)		0.233***	0.215***		0.137***	0.128***
		(0.045)	(0.045)		(0.046)	(0.046)
Predicate Device Recall by Diff. Manufacturer: (b)		0.199***			0.131***	
		(0.040)			(0.043)	
Predicate Device Recall by Diff. Manufacturer			0.189**			0.168**
- High Tech. Proximity: (c)			(0.075)			(0.075)
Predicate Device Recall by Diff. Manufacturer			0.078			0.043
- Low Tech. Proximity: (d)			(0.082)			(0.090)
Log(1+Age)	-0.107	-0.089	-0.063	-0.114	-0.099	-0.076
	(0.068)	(0.067)	(0.073)	(0.083)	(0.082)	(0.086)
Log(1+Number 510K Devices by Firm)	0.050***	0.049***	0.045***	0.042***	0.042***	0.040***
	(0.010)	(0.010)	(0.010)	(0.010)	(0.009)	(0.009)
Log(1+Number of Devices in Product Code)	0.080	0.083	0.117	0.067	0.067	0.083
	(0.070)	(0.071)	(0.073)	(0.068)	(0.069)	(0.068)
Log(1+Number of New Devices in Product Code)	0.064*	0.063*	0.060*	0.051*	0.050	0.047
	(0.033)	(0.033)	(0.034)	(0.031)	(0.031)	(0.031)
Log(1+Ave. Number of Predicates by Product Code)	0.006	0.010	0.008	0.022	0.024	0.027
	(0.053)	(0.053)	(0.053)	(0.049)	(0.049)	(0.048)
Approval Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Product Code Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	1,886	1,886	1,886	1,885	1,885	1,885
Adjusted R-squared	0.227	0.225	0.214	0.221	0.219	0.215
p-value for the difference (a) and (b)		0.583			0.931	
p-value for the difference (c) and (d)			0.370			0.287

Table 6. Effects of Predicate Device Recall on Innovation Strategies of Follow-on Device Manufacturers

This table reports results from the firm-level OLS regressions of the number of new 510(k) devices and the diversification of 510(k) device portfolios on predicate device recall. The sample consists of 109,875 manufacturer-year observations for 11,222 firms for the sample period from 2002 to 2021. In columns (1) to (3), the dependent variable is *Log(1+Number of New 510k Devices at T_{+1})* that is the log of one plus the total number of newly cleared 510(k) devices by the follow-on device manufacturer one year after the predicate device recall. In columns (4) to (6), the dependent variable is *Product Code Diversification at T_{+1} (Inv. HHI)* that is the inverse of the Herfindahl-Hirschman Index (HHI) of the device portfolio across different product codes measured one year after the predicate device recall. In columns (1) and (4), the key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In columns (2) and (5), the key independent variable is *Predicate Device Recall by Same (Diff.) Manufacturer* that is one if the follow-on device's predicate produced by the same (a different) manufacturer is recalled in a given year and zero otherwise. In columns (3) and (6), we decompose *Predicate Device Recall by Diff. Manufacturer* into high vs. low technological proximity. Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices. In all columns, we control for year fixed effects and manufacturer fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by industry. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Log (1+Number of New 510k Devices at T_{+1})			Product Code Diversification at T_{+1} (Inv. HHI)		
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.002			0.002		
	(0.008)			(0.003)		
Predicate Device Recall		0.021	0.022		0.029***	0.029***
by Same Manufacturer: (a)		(0.029)	(0.029)		(0.006)	(0.006)
Predicate Device Recall		-0.002			-0.000	
by Diff. Manufacturer: (b)		(0.008)			(0.003)	
Predicate Device Recall by Diff. Manufacturer			-0.015			0.009***
- High Tech. Proximity: (c)			(0.014)			(0.003)
Predicate Device Recall by Diff. Manufacturer			-0.007			-0.006**
- Low Tech. Proximity: (d)			(0.008)			(0.003)
Log(1+Age)	-0.005	-0.005	-0.005	-0.015***	-0.015***	-0.015***
	(0.006)	(0.006)	(0.006)	(0.002)	(0.002)	(0.002)
Log(1+Number of Devices in Product Code)	-0.022**	-0.022**	-0.022**	-0.023***	-0.023***	-0.023***
	(0.008)	(0.008)	(0.008)	(0.007)	(0.007)	(0.007)
Log(1+Number of New Devices in	0.026***	0.026***	0.026***	-0.002	-0.002	-0.002
Product Code)	(0.008)	(0.008)	(0.008)	(0.002)	(0.002)	(0.002)
Log(1+Ave. Number of Predicates by	-0.016**	-0.016**	-0.016**	0.006***	0.006***	0.006***
Product Code)	(0.006)	(0.006)	(0.006)	(0.002)	(0.002)	(0.002)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Manufacturer Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	109,875	109,875	109,875	109,875	109,875	109,875
Adjusted R-squared	0.455	0.455	0.455	0.944	0.944	0.944
p-value for the difference (a) and (b)		0.4532			0.001***	
p-value for the difference (c) and (d)			0.6498			0.000***

Table 7. Effects of Predicate Device Recall on Follow-on Device Citations

This table reports results from the device-level OLS regressions of the number of follow-on device citations by other manufacturers on predicate device recall. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). To address the self-citation concern, we only consider citations by the devices produced by other manufacturers. The sample consists of 105,239 device-year observations for 12,312 medical devices cleared by 510(k) (4,888 firms) for the sample period from 2002 to 2021. In columns (1) to (3), the dependent variable is *Log(1+Number of Citation by Other Manufacturers at* T_{+1}*)* that is the log of one plus the total number of follow-on device citations as a predicate device by other manufacturers one year after the predicate device recall. In columns (4) to (6), the dependent variable is *Log(1+Number of Citation by Other Manufacturers at* $T_{[+1,+3]}$*)* that is the log of one plus the total number of follow-on device citations as a predicate device by other manufacturers during the three years after predicate device recall. In columns (1) and (4), the key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In columns (2) and (5), the key independent variable is *Predicate Device Recall by Same (Diff.) Manufacturer* that is one if the follow-on device's predicate produced by the same (a different) manufacturer is recalled in a given year and zero otherwise. In columns (3) and (6), we decompose *Predicate Device Recall by Diff. Manufacturer* into high vs. low technological proximity. Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Log(1+Number of Citations by Other Manufacturers at T_{+1})			Log(1+Number of Citations by Other Manufacturers at $T_{[+1,+3]}$)		
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.005			0.026***		
	(0.006)			(0.008)		
Predicate Device Recall by Same Manufacturer:(a)		-0.020**	-0.020**		-0.036***	-0.036***
		(0.009)	(0.008)		(0.011)	(0.009)
Predicate Device Recall by Diff. Manufacturer:(b)		0.022***			0.060***	
		(0.008)			(0.011)	
Predicate Device Recall by Diff. Manufacturer			0.004			0.040**
- High Tech. Proximity: (c)			(0.018)			(0.020)
Predicate Device Recall by Diff. Manufacturer			0.028*			0.067***
- Low Tech. Proximity: (d)			(0.015)			(0.018)
Log(1+Age)	0.002	0.002	0.002	-0.046***	-0.046***	-0.046***
	(0.004)	(0.004)	(0.003)	(0.007)	(0.007)	(0.003)
Log(1+Number 510K Devices by Firm)	-0.013*	-0.015**	-0.013***	-0.039***	-0.043***	-0.038***
	(0.007)	(0.007)	(0.005)	(0.011)	(0.011)	(0.005)
Log(1+Number of Devices	-0.089***	-0.091***	-0.090***	-0.154***	-0.158***	-0.154***
in Product Code)	(0.012)	(0.012)	(0.006)	(0.021)	(0.021)	(0.007)
Log(1+Number of New Devices	0.006*	0.007*	0.006***	-0.000	0.000	-0.000
in Product Code)	(0.003)	(0.003)	(0.002)	(0.005)	(0.005)	(0.003)
Log(1+Ave. Number of Predicates	0.001	0.001	0.001	0.001	0.000	0.001
by Product Code)	(0.005)	(0.005)	(0.003)	(0.008)	(0.008)	(0.004)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	105,239	105,239	105,239	105,239	105,239	105,239
Adjusted R-squared	0.169	0.169	0.169	0.391	0.392	0.392
p-value for the difference (a) and (b)		0.004***			0.000***	
p-value for the difference (c) and (d)			0.291			0.310

Table 8. Effects of Predicate Device Recall on Follow-on Device Manufacturers' Financial Performance

This table reports results from the firm-level OLS regressions of follow-on device manufacturers' financial performance on predicate device recall. We use the full sample (before sibling matching) that consists of 2,479 manufacturer-year observations for 392 firms for the sample period from 2002 to 2021. In columns (1) to (3), the dependent variable is *Tobin's q* at $T_{[+1,+3]}$ of the follow-on device manufacturer during the three years after the event year of a predicate device recall. In columns (4) to (6), the dependent variable is *Sales Growth* at $T_{[+1,+3]}$ of the follow-on device manufacturer during the three years after the event year of a predicate device recall. In columns (1) and (4), the key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In columns (2) and (5), the key independent variable is *Predicate Device Recall by Same (Diff.) Manufacturer* that is one if the follow-on device's predicate produced by the same (a different) manufacturer is recalled in a given year and zero otherwise. In columns (3) and (6), we decompose *Predicate Device Recall by Diff. Manufacturer* into high vs. low technological proximity. Technological proximity is the cosine similarity score of cumulative Cooperative Patent Classification (CPC) of all patents whose assignees are the two manufacturers of predicate and follow-on devices. In all columns, we control for year fixed effects and manufacturer fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by manufacturer. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Tobin's *q* at $T_{[+1,+3]}$			Sales Growth at $T_{[+1,+3]}$		
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.033			0.002		
	(0.051)			(0.007)		
Predicate Device Recall by Same Manufacturer: (a)		-0.108*	-0.098		-0.017**	-0.017**
		(0.059)	(0.057)		(0.008)	(0.008)
Predicate Device Recall by Diff. Manufacturer: (b)		0.170***			0.016**	
		(0.057)			(0.007)	
Predicate Device Recall by Diff. Manufacturer			-0.060			0.002
- High Tech. Proximity: (c)			(0.089)			(0.011)
Predicate Device Recall by Diff. Manufacturer			0.197**			0.020**
- Low Tech. Proximity: (d)			(0.071)			(0.009)
Log(1+Age)	-0.174	-0.168	-0.175	-0.017	-0.017	-0.018
	(0.119)	(0.118)	(0.120)	(0.013)	(0.013)	(0.013)
Log(1+Number 510K Devices by Firm)	-0.186	-0.184	-0.177	-0.035*	-0.034*	-0.034*
	(0.140)	(0.141)	(0.141)	(0.019)	(0.019)	(0.018)
Log(1+Number of Devices in Product Code)	0.069	0.060	0.066	-0.005	-0.006	-0.006
	(0.106)	(0.105)	(0.104)	(0.015)	(0.015)	(0.015)
Log(1+Number of New Devices in Product Code)	-0.115	-0.107	-0.112	-0.002	-0.001	-0.001
	(0.067)	(0.065)	(0.066)	(0.010)	(0.010)	(0.010)
Log(1+Ave. Number of Predicates by Product Code)	0.072	0.071	0.075	0.008	0.008	0.008
	(0.094)	(0.093)	(0.093)	(0.009)	(0.009)	(0.009)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Manufacturer Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,479	2,479	2,479	2,479	2,479	2,479
Adjusted R-squared	0.765	0.766	0.765	0.499	0.500	0.500
p-value for the difference (a) and (b)		0.006***			0.005***	
p-value for the difference (c) and (d)			0.018**			0.159

Internet Appendix for "Diffused Errors along Technology Spillovers: Evidence from the 510(k) Medical Device Market"

Section A. FDA Medical Device Review Program – 510(k) and PMA

The Food and Drug Administration (FDA) is responsible for the oversight of medical devices marketed in the U.S. It classifies medical devices into three classes "based on the level of control necessary to assure the safety and effectiveness of the device,"[20] which is associated with the level of risk the device poses to patients. Class 1 is for low-risk medical devices, Class 2 is for moderate-risk medical devices, and Class 3 is for high-risk medical devices. Unless exempt under FDA regulations (self-registration), all medical devices are subject to one of the two types of FDA premarket reviews – premarket approval (PMA) and 510(k) premarket notification - before they are legally marketed in the U.S.

Premarket approval (PMA), which is a more stringent type of these two reviews, evaluates whether a new medical device has sufficient evidence regarding safety and effectiveness for its intended use. During the PMA review, device manufacturers must provide evidence that offers reasonable assurance that new devices are safe and effective, typically including clinical data. Class 3 medical devices generally need to go through this PMA,[21] and only about 1% of new medical devices go through the PMA process (GAO 2009). A successful review outcome of the PMA process results in FDA approval.

510(k) premarket notification (also called PMN) is a less stringent type of new medical device review, and Class 1[22] and Class 2 devices are eligible for the 510(k) review. The 510(k) process has become the main path for the FDA to review a new medical device, consisting of 31% of all new medical device reviews (GAO 2009).[23] During the 510(k) review, device manufacturers only need to demonstrate substantial equivalence (SE) to one of the existing devices already legally

[20] https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
[21] One exception is that if a Class 3 devices has only minor differences from already approved predicate devices, the Class 3 device may be reclassified as a Class 1 or 2 device and is eligible for 510(k) instead of PMA.
[22] The majority of Class 1 devices go to the market with self-registration.
[23] 67% of new medical devices are exempted from the FDA review and the remaining 1% includes medical devices that enters the market via other means, such as the humanitarian device exemption process for rare diseases or conditions (GAO 2009).

on the market. The existing medical device that a new 510(k) applicant claims substantial equivalence to is called a predicate device.

A predicate device can be any legally marketed medical device in the U.S. including 1) a device that is on the market through 510(k) program clearance, 2) a device that was on the market before the Medical Device Regulation Act or Medical Device Amendments of 1976,[24] 3) a Class 3 device that was approved through PMA and later reclassified as a Class 1 or Class 2 device, or 4) 510(k)-exempt device.[25] To be substantially equivalent to an existing device, a new medical device must have either the same intended use and the same technological characteristics as the predicate device or the same intended use but different technological characteristics as the predicate device as long as it is safe and effective as the legally marketed device and does not raise different questions of safety and effectiveness.[26] Device manufacturers are required to notify the FDA 90 days before they intend to market a device. A successful review outcome of the 510(k) process results in FDA clearance. Compared to the PMA process, a decision on a 510(k) submission is made faster, and final clearance can be granted usually within 90 days.

[24] FDA was given the authority to begin regulating all medical devices on May 28, 1976.
[25] https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices
[26] https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

Section B. Extraction of Predicate Information

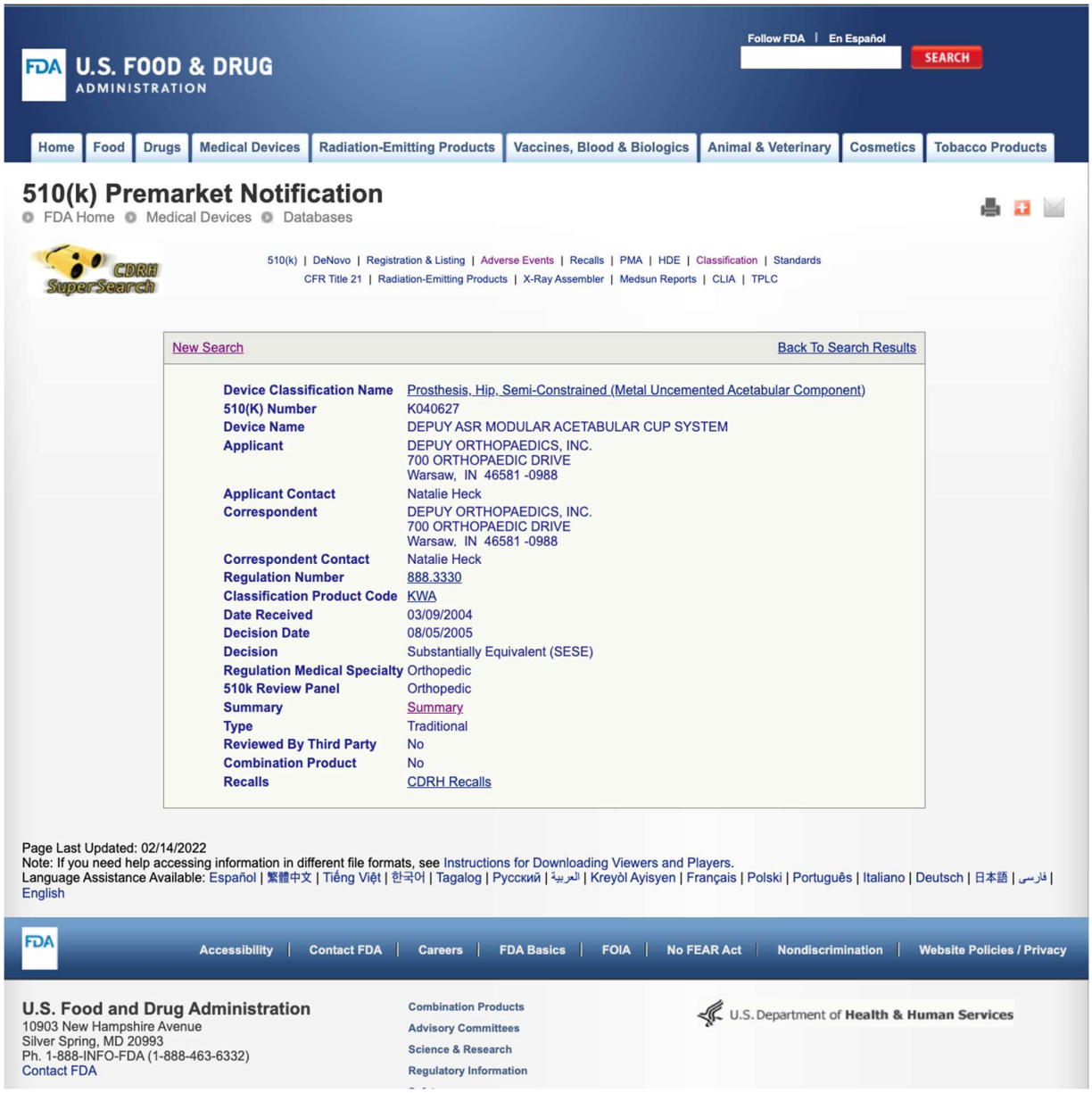
The designated webpage with administrative details and the summary of 510(k) premarket notification for each 510(k) device is available from the FDA's website.[27] Figure IA1 shows an example of the 510(k) premarket notification webpage for DePuy ASR (510(k) number: K040627), an artificial hip replacement device manufactured by DePuy Orthopaedics. Such webpages include a link to the summary of 510(k) premarket notification ("Summary") in PDF format. The web addresses of the PDF summary documents follow a standard format. For example, the PDF summary document of DePuy ASR with 510 (k) number of K040627 is located at https://www.accessdata.fda.gov/cdrh_docs/pdf4/K040627.pdf. The numerical digits that start with the letter "K" in the web address are uniquely mapped to the 510(k) number. Therefore, we are able to electronically process and download all PDF summary files for all 510(k) devices in our sample.

Figure IA2 shows the first page of the PDF summary of 510(k) premarket notification for DePuy ASR. The summary document of each 510(k) device lists its predicates that the 510(k) device claims "substantially equivalence". One 510(k) device can have multiple predicates whose ID starts with "K" for another 510(k) device or "P" for a PMA device. To extract 510(k) or PMA numbers of those predicates, we first convert the PDF summary for each 510(k) device to a text document and then electronically process the text file with Python programming. Some 510(k) devices approved in the early part of our sample period do not have machine-readable summary documents (i.e., scanned documents with handwriting or a nonstandard format). For those cases, we manually read the contents of the documents and extract predicate information.

Some devices do not have a link to a PDF summary file, and some PDF summary files do not contain predicate device information. Those cases comprise 27% of the entire 510(k) devices from the FDA data, and we exclude them from our sample.

[27] The FDA's website manages the 510(k) Premarket Notification page where users can search the releasable 510(k) database by various search queries including 510(k) number, Product code, and Device name. See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

Figure IA1. An Example of 510(k) Premarket Notification



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510(k) Premarket Notification

FDA Home > Medical Devices > Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To Search Results

Device Classification Name	Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component)
510(K) Number	K040627
Device Name	DEPUY ASR MODULAR ACETABULAR CUP SYSTEM
Applicant	DEPUY ORTHOPAEDICS, INC. 700 ORTHOPAEDIC DRIVE Warsaw, IN 46581 -0988
Applicant Contact	Natalie Heck
Correspondent	DEPUY ORTHOPAEDICS, INC. 700 ORTHOPAEDIC DRIVE Warsaw, IN 46581 -0988
Correspondent Contact	Natalie Heck
Regulation Number	888.3330
Classification Product Code	KWA
Date Received	03/09/2004
Decision Date	08/05/2005
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Orthopedic
510k Review Panel	Orthopedic
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No
Recalls	CDRH Recalls

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Figure IA2. An Example of PDF 510(K) Summary

K040627 (pg 1 of 2)

AUG 5 - 2005

510(k) Summary

NAME OF FIRM:	DePuy Orthopaedics, Inc. PO Box 988 700 Orthopaedics Warsaw, IN 46581-0988
510(k) CONTACT:	Natalie Heck Manager, Regulatory Affairs
TRADE NAME:	DePuy ASR™ Modular Acetabular Cup System
COMMON NAME:	Femoral Hip Prosthesis
CLASSIFICATION:	**Class III per 21 CFR 888.3330 Hip Joint metal/metal semiconstrained, with an uncemented acetabular component prosthesis**
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Pinnacle® Metal-on-Metal Acetabular Cup Line (K002883 & K003523) Wright Medical Metal TRANSCEND® Articulation System (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156)

DEVICE DESCRIPTION:

The DePuy ASR™ Modular Acetabular Cup System is comprised of a one-piece metal acetabular cup, a unipolar femoral head, and a taper sleeve adapter.

Section C. Extraction of Detailed Recall Information

Medical device recall data are available from the FDA's website.[28] The downloadable data file from the FDA site contains an administrative summary of each recall case, including "WEB_ADDRESS" which refers to a webpage address for more detailed recall information. The detailed information includes recall date, date posted, recall status, recall number, recall event ID, device ID (510(k) or PMA number), product classification, product textual description, recalling firm/manufacturer, contact information, manufacturer reason for the recall, FDA-determined cause, action taken, quantity in commerce, and geographic distribution (worldwide vs. domestic). Figure IA3 presents a snapshot of those items for a Class 2 Device Recall DEPUY ASR ACETABULAR CUP SYSTEM.[29]

The structured format of the web pages allows us to extract all information on the pages and compile a comprehensive database of medical device recalls. We process all web pages, totaling 43,293 recall cases in the downloadable data file from the FDA site, and find that 72.7% of the cases contain device ID information of either 510(k) or PMA numbers.

[28] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm

[29] For the full information on Class 2 Device Recall DEPUY ASR ACETABULAR CUP SYSTEM, for example, visit the webpage at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=95531.

Figure IA3. An Example of Recall Webpages



See Related Information

Class 2 Device Recall DEPUY ASR ACETABULAR CUP SYSTEM

Date Initiated by Firm	August 23, 2010
Date Posted	March 24, 2011
Recall Status[1]	Terminated [3] on August 29, 2013
Recall Number	Z-1750-2011
Recall Event ID	57177
510(K)Number	K040627
Product Classification	Prosthesis, hip, semi-constrained (metal, uncemented acetabular component) - **Product Code** KWA
Product	ASR ACETABULAR IMPLANT 46, DEPUY ASR ACETABULAR CUP SYSTEM, DePuy Articular Surface Replacement (ASR) Hip Prosthesis System The DePuy ASR Acetabular Cup System is comprised of a one-piece metal acetabular cup, a unipolar femoral head, and a taper sleeve adapter. The acetabular component is designed as a cobalt-chrome molybdenum (CoCrMo) alloy one-piece cup with Porocoat¿ porous coating and is available in outer diameter sizes 44mm through 62mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (H-A) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups. The DePuy ASR TM Acetabular Cup System is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.
Code Information	Part Number 999800746, Size 46, All lots
Recalling Firm/ Manufacturer	Depuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw IN 46582-3994
For Additional Information Contact	ASR Helpline 888-627-2677
Manufacturer Reason for Recall	As part of our ongoing post-market surveillance of all products, DePuy is continually evaluating data from a variety of sources including national joint replacement registries, published literature, company sponsored clinical trials, internal complaints data and unpublished clinical research reports. DePuy Orthopaedics issued a Field Safety Notice in March 2010 after receiving new data from the
FDA Determined Cause [2]	Device Design
Action	DePuy Orthopaedics issued a Field Safety Notice in March 2010 to all affected customers. The Notice identified the product, the problem, and the action to be taken by the customer. Customers were instructed to share the Field Safety Notice with their organization and any organization where the ASR products may have been transferred. Customer were instructed not to implant the ASR devices. Patients who received the ASR System should be informed of this recall and instructed to return for a follow up visit.

Table IA1. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: No Control Variable

This table reports results from the regressions of follow-on device recall on predicate device recall, as in Table 3, without control variables. In columns (1)-(6), we use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In column (7), we use the full sample (before sibling matching) that consists of 400,441 device-year observations for 44,625 medical devices cleared by 510(k). In all columns except for column (4), the linear probability model regression is used. The dependent variable is *Follow-on Device Recall at T_0* at the event year of predicate recall except for columns (2), (5), and (6). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we regress *Follow-on Device Recall at T_0* on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at $T_{[0,+2]}$* that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*) as the main independent variable. In column (7), we reestimate the regression in column (1) using the full sample. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall						
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls	Full Sample
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Predicate Device Recall	0.100***	0.088***	0.083***	1.607***			0.101***
	(0.012)	(0.010)	(0.010)	(0.108)			(0.006)
Number of Predicate Device Recalls					0.061***		
					(0.004)		
Ratio of Predicate Device Recall						0.185***	
						(0.022)	
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No	No
Observations	114,601	114,601	112,741	10,669	114,601	114,601	400,441
Adjusted R-squared	0.104	0.253	0.079	0.130	0.059	0.061	0.098

Table IA2. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Logit Model

This table reports results from the logit model regressions of follow-on device recall on predicate device recall. In columns (1)-(4), we use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recall[ed] predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 105,817 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In column (5), we use the full sample (before sibling matching) that consists of 374,352 device-year observations. The key independent variable is *Predicate Device Recall* that is of one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we regress *Follow-on Device Recall at* T_0 at the event year of predicate recall on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at* $T_{[0,+2]}$ that is of one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we use the total number of predicate recalls as the main independent variable. In column (4), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*). In column (5), we use the full sample instead of using the sibling-pair sample and reestimate the regression in column (1). In all columns, we control for year fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall				
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls	Full Sample
Independent Variable	(1)	(2)	(3)	(4)	(5)
Predicate Device Recall	2.566***	1.894***			2.380***
	(0.120)	(0.116)			(0.063)
Number of Predicate Device Recalls			1.051***		
			(0.159)		
Ratio of Predicate Device Recall				3.470***	
				(0.158)	
Log(1+Age)	-0.017	-0.208***	-0.074	0.028	-0.073**
	(0.053)	(0.043)	(0.050)	(0.058)	(0.029)
Log(1+Number 510K Devices by Firm)	0.203***	0.194***	0.211***	0.204***	0.235***
	(0.033)	(0.033)	(0.035)	(0.034)	(0.019)
Log(1+Number of Devices in Product Code)	-0.190**	-0.195***	-0.238***	-0.215***	0.023
	(0.081)	(0.074)	(0.085)	(0.083)	(0.071)
Log(1+Number of New Devices in Product Code)	0.091	0.063	0.131	0.113	-0.099
	(0.093)	(0.084)	(0.102)	(0.096)	(0.081)
Log(1+Ave. Number of Predicates by Product Code)	-0.014	0.058	0.055	0.093	0.081
	(0.138)	(0.128)	(0.140)	(0.140)	(0.092)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	No	No	No	No	No
Product Code x Year Fixed Effects	No	No	No	No	No
Observations	105,817	105,817	105,817	105,817	374,352
Pseudo R-squared	0.097	0.072	0.072	0.089	0.110

Table IA3. Recall Propensity of Follow-on Devices after Predicate Device Recall using Sibling-pair Sample: a Further Matched Sibling-pair sample

This table reports results from the regressions of follow-on device recall on predicate device recall with a further matched sibling pair sample for within-pair technological similarity. We use the further refined sibling-pair matched sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate) only when there exists at least one follow-on device that cites both recalled and unrecalled devices within the sibling pair. Then the follow-on devices that cite both recalled and unrecalled devices are dropped from the sample after defining a further refined sample. The sample consists of 23,074 device-year observations for 2,587 medical devices cleared by 510(k) for the sample period from 2002 to 2021. In all columns except for column (4), the linear probability model regression is used. The dependent variable is *Follow-on Device Recall at T_0* at the event year of predicate recall except for columns (2), (5), and (6). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we regress *Follow-on Device Recall at T_0* on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at $T_{[0,+2]}$* that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*) as the main independent variable. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall					
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.092***	0.114***	0.090***	1.662***		
	(0.018)	(0.023)	(0.026)	(0.249)		
Number of Predicate Device Recalls					0.086***	
					(0.018)	
Ratio of Predicate Device Recall						0.114***
						(0.023)
Log(1+Age)	-0.006	0.007**	0.006	0.580**	0.008**	0.007**
	(0.007)	(0.003)	(0.004)	(0.266)	(0.003)	(0.003)
Log(1+Number 510K Devices by Firm)	-0.009	-0.005	-0.004	-0.516	-0.005	-0.005
	(0.011)	(0.004)	(0.004)	(0.348)	(0.004)	(0.004)
Log(1+Number of Devices in Product Code)	-0.036**	-0.013		-0.895	-0.013	-0.013
	(0.017)	(0.008)		(0.665)	(0.008)	(0.008)
Log(1+Number of New Devices in Product Code)	-0.003	0.001		0.253	0.001	0.001

	(0.004)	(0.002)		(0.217)	(0.002)	(0.002)
Log(1+Ave. Number of Predicates by Product Code)	0.008*	0.005		0.386	0.005	0.005
	(0.005)	(0.004)		(0.306)	(0.004)	(0.004)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No
Observations	23,074	23,074	21,386	2,079	23,074	23,074
Adjusted R-squared	0.228	-0.122	0.041	0.121	-0.000	0.003
Number of Unique Devices	2,587	2,587	2,396	210	2,587	2,587

Table IA4. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Class 2 Devices Only

This table reports results from the regressions of follow-on device recall on predicate device recall using only devices in class 2. In columns (1)-(6), we use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall, while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 107,928 device-year observations for 12,077 medical devices cleared by 510(k) (4,773 firms) for the sample period from 2002 to 2021. In column (7), we use the full sample (before sibling matching) that consists of 372,005 device-year observations for 41,300 medical devices cleared by 510(k). In all columns except for column (4), the linear probability model regression is used. The dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall except for columns (2), (5), and (6). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we regress *Follow-on Device Recall at* T_0 on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*) as the main independent variable. In column (7), we reestimate the regression in column (1) using the full sample. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ∗∗∗, ∗∗, and ∗ indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall						
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling For Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Device Recalls	Using Ratio of Predicate Device Recalls	Full Sample
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Predicate Device Recall	0.103***	0.090***	0.086***	1.622***			0.104***
	(0.012)	(0.010)	(0.010)	(0.112)			(0.007)
Number of Predicate Device Recalls					0.062***		
					(0.005)		
Ratio of Predicate Device Recall						0.193***	
						(0.023)	
Log(1+Age)	0.008***	-0.001	0.008***	0.773***	0.008***	0.009***	0.011***
	(0.002)	(0.004)	(0.003)	(0.147)	(0.002)	(0.003)	(0.002)
Log(1+Number 510K Devices by Firm)	-0.005**	-0.010*	-0.005**	-0.159	-0.004**	-0.005**	-0.007***
	(0.002)	(0.005)	(0.003)	(0.156)	(0.002)	(0.002)	(0.002)
Log(1+Number of Devices in Product Code)	-0.008**	-0.022***		-0.486*	-0.008**	-0.008**	-0.003
	(0.004)	(0.008)		(0.254)	(0.003)	(0.004)	(0.002)

Log(1+Number of New Devices in Product Code)	-0.001	-0.006*		0.047	-0.001	-0.001	-0.000
	(0.001)	(0.003)		(0.087)	(0.001)	(0.002)	(0.001)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.003		-0.126	-0.001	-0.001	-0.000
	(0.002)	(0.003)		(0.129)	(0.002)	(0.002)	(0.001)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No	No
Observations	107,928	107,928	106,270	10,455	107,928	107,928	372,005
Adjusted R-squared	0.106	0.255	0.080	0.138	0.060	0.063	0.102

Table IA5. Recall Propensity of Follow-on Device after Predicate Device Recall using Sibling-pair Sample: Identical Recall Reasons

This table reports results from the regressions of follow-on device recall on predicate device recall. In columns (1)-(6), we use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In column (7), we use the full sample (before sibling matching) that consists of 400,441 device-year observations for 44,625 medical devices cleared by 510(k). In all columns except for column (4), the linear probability model regression is used. The dependent variable is *Follow-on Device Recall with Identical Reasons as Predicate Device Recalls* at the event year of predicate recall except for columns (2), (5), and (6), which is one if the follow-on device is recalled for the same cause specified by the FDA (e.g., component design/selection, device design, process design, software design, storage, labeling, counterfeit, packaging, etc.) as its predicate recalls in a given year, and zero otherwise. The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (2), we use *Follow-on Device Recall with Identical Reasons as Predicate Device Recalls at* $T_{[0,+2]}$ that is one if a follow-on device is recalled during the three years since the predicate recall for the same cause specified by the FDA as its predicate recalls and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*) as the main independent variable. In column (7), we reestimate the regression in column (1) using the full sample. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall with Identical Reasons as Predicate Device Recalls						
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls	Full Sample
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Predicate Device Recall	0.107***	0.105***	0.102***	4.757***			0.108***
	(0.013)	(0.012)	(0.011)	(0.303)			(0.008)
Number of Predicate Device Recalls					0.067***		
					(0.004)		
Ratio of Predicate Device Recall						0.195***	
						(0.024)	
Log(1+Age)	0.004**	0.004**	0.003*	1.278***	0.003**	0.004**	0.005***
	(0.002)	(0.002)	(0.002)	(0.312)	(0.001)	(0.002)	(0.001)
Log(1+Number 510K Devices by Firm)	-0.002	-0.002	-0.002	-0.166	-0.001	-0.002	-0.002*
	(0.002)	(0.002)	(0.002)	(0.358)	(0.001)	(0.002)	(0.001)
Log(1+Number of Devices in Product Code)	-0.001	-0.002		-0.162	-0.001	-0.002	0.000
	(0.002)	(0.002)		(0.570)	(0.002)	(0.002)	(0.001)

Log(1+Number of New Devices in Product Code)	-0.001	-0.001		-0.384*	-0.001	-0.001	-0.001
	(0.001)	(0.001)		(0.213)	(0.001)	(0.001)	(0.000)
Log(1+Ave. Number of Predicates by Product Code)	0.000	-0.000		0.308	0.001	0.000	0.000
	(0.001)	(0.001)		(0.251)	(0.001)	(0.001)	(0.001)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No	No
Observations	114,601	114,601	112,741	2,976	114,601	114,601	400,441
Adjusted R-squared	0.157	0.153	0.159	0.500	0.126	0.127	0.151

Table IA6. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Recall Classes

This table reports results from the linear probability model regressions of follow-on device recall on predicate recall by predicate device recall classes. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In columns (1) to (4), the dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall. In columns (5) to (8), the dependent variable is *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on medical device is recalled during the three years since the predicate device recall and zero otherwise. We decompose *Predicate Device Recall* by recall classes (*class I*: recalls for products that could cause serious injury or death; *class II*: recalls for products that might cause serious injury or temporary illness; *class III*: recalls for products that are unlikely to cause injury or illness, but violate FDA regulations.). In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Follow-on Device Recall at T_0				Follow-on Device Recall at $T_{[0-+2]}$			
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Predicate Device Recall Class I	0.103***			0.100***	0.089***			0.087***
	(0.028)			(0.028)	(0.024)			(0.026)
Predicate Device Recall Class II		0.100***		0.100***		0.086***		0.085***
		(0.013)		(0.013)		(0.011)		(0.011)
Predicate Device Recall Class III			0.059***	0.049**			0.074***	0.065***
			(0.019)	(0.020)			(0.021)	(0.022)
Log(1+Age)	0.008***	0.008***	0.008***	0.008***	-0.001	-0.001	-0.001	-0.001
	(0.003)	(0.002)	(0.003)	(0.002)	(0.004)	(0.003)	(0.004)	(0.003)
Log(1+Number 510K Devices by Firm)	-0.004*	-0.004*	-0.005*	-0.004*	-0.011*	-0.010*	-0.011**	-0.010*
	(0.002)	(0.002)	(0.002)	(0.002)	(0.005)	(0.005)	(0.005)	(0.005)
Log(1+Number of Devices in Product Code)	-0.008**	-0.007*	-0.008**	-0.006*	-0.019**	-0.017**	-0.019**	-0.017**
	(0.004)	(0.003)	(0.004)	(0.003)	(0.008)	(0.008)	(0.008)	(0.008)
Log(1+Number of New Devices in Product Code)	-0.002	-0.002	-0.002	-0.002	-0.007**	-0.006**	-0.007**	-0.006**
	(0.002)	(0.001)	(0.002)	(0.001)	(0.003)	(0.003)	(0.003)	(0.003)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.001	-0.001	-0.001	-0.003	-0.003	-0.003	-0.003
	(0.002)	(0.002)	(0.002)	(0.002)	(0.003)	(0.003)	(0.003)	(0.003)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Observations	114,601	114,601	114,601	114,601	114,601	114,601	114,601	114,601
Adjusted R-squared	0.039	0.056	0.038	0.057	0.247	0.253	0.247	0.253

Table IA7. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Technical Errors in Predicate Recalls

This table reports results from the linear probability model regressions of follow-on device recall on predicate recall by technical errors in predicate recalls. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In columns (1) to (3), the dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall. In columns (4) to (6), the dependent variable is *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on medical device is recalled during the three years since the predicate device recall and zero otherwise. We decompose *Predicate Device Recall* by FDA-specified causes for recall into high vs. low relevance to technical errors that can be passed down. The high-relevance group includes component design/selection, device design, process design, software design, etc. The low relevance group includes errors in storage, labeling, counterfeit, packaging, etc. In all columns, we control for the year fixed effects and the device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ∗∗∗, ∗∗, and ∗ indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Follow-on Device Recall at T_0			Follow-on Device Recall at $T_{[0-+2]}$		
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.111***		0.113***	0.098***		0.099***
- High Relevance to Technical Errors: (a)	(0.015)		(0.015)	(0.013)		(0.013)
Predicate Device Recall		0.065***	0.072***		0.054***	0.060***
- Low Relevance to Technical Errors: (b)		(0.010)	(0.010)		(0.011)	(0.011)
Log(1+Age)	0.008***	0.008***	0.008***	-0.001	-0.001	-0.001
	(0.002)	(0.003)	(0.002)	(0.003)	(0.004)	(0.003)
Log(1+Number 510K Devices by Firm)	-0.004*	-0.004*	-0.004*	-0.010**	-0.011*	-0.010*
	(0.002)	(0.002)	(0.002)	(0.005)	(0.005)	(0.005)
Log(1+Number of Devices in Product Code)	-0.007**	-0.008*	-0.006*	-0.018**	-0.018**	-0.017**
	(0.003)	(0.004)	(0.003)	(0.008)	(0.008)	(0.008)
Log(1+Number of New Devices in Product Code)	-0.002	-0.002	-0.002	-0.006**	-0.007**	-0.006**
	(0.001)	(0.002)	(0.001)	(0.003)	(0.003)	(0.003)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.001	-0.001	-0.003	-0.003	-0.003
	(0.002)	(0.002)	(0.002)	(0.003)	(0.003)	(0.003)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	114,601	114,601	114,601	114,601	114,601	114,601
Adjusted R-squared	0.055	0.040	0.058	0.253	0.248	0.254

Table IA8. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Duration from Predicate

This table reports results from the linear probability model regressions of follow-on device recall on predicate recall. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 114,601 device-year observations for 12,890 medical devices cleared by 510(k) (5,103 firms) for the sample period from 2002 to 2021. In columns (1) to (3), the dependent variable is *Follow-on Device Recall at T_0* at the event year of predicate recall. In columns (4) to (6), the dependent variable is *Follow-on Device Recall at $T_{[0,+2]}$* that is one if a follow-on medical device is recalled during the three years since the predicate device recall and zero otherwise. We decompose *Predicate Device Recall* by the sample median of duration from their predicate devices. The duration is the shortest interval between the approval year of the focal device and the approval year of its predicate devices. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Follow-on Device Recall at T_0			Follow-on Device Recall at $T_{[0-+2]}$		
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.116***		0.116***	0.102***		0.102***
- Short Duration between Predicate and Focal: (a)	(0.015)		(0.015)	(0.012)		(0.012)
Predicate Device Recall		0.062***	0.063***		0.054***	0.055***
- Long Duration between Predicate and Focal: (b)		(0.010)	(0.010)		(0.010)	(0.010)
Log(1+Age)	0.007***	0.008***	0.008***	-0.001	-0.001	-0.001
	(0.002)	(0.003)	(0.002)	(0.003)	(0.004)	(0.003)
Log(1+Number 510K Devices by Firm)	-0.004*	-0.005*	-0.004*	-0.010*	-0.011*	-0.010*
	(0.002)	(0.002)	(0.002)	(0.005)	(0.005)	(0.005)
Log(1+Number of Devices in Product Code)	-0.006*	-0.008**	-0.006*	-0.017**	-0.019**	-0.017**
	(0.003)	(0.004)	(0.003)	(0.008)	(0.008)	(0.008)
Log(1+Number of New Devices in Product Code)	-0.002	-0.002	-0.002	-0.006**	-0.007**	-0.006**
	(0.001)	(0.002)	(0.001)	(0.003)	(0.003)	(0.003)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.001	-0.001	-0.003	-0.003	-0.003
	(0.002)	(0.002)	(0.002)	(0.003)	(0.003)	(0.003)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	114,601	114,601	114,601	114,601	114,601	114,601
Adjusted R-squared	0.056	0.040	0.059	0.253	0.248	0.254
p-value for the difference (a) and (b)			0.00***			0.00***

Table IA9. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Siblings with a Single Predicate

This table reports results from the regressions of follow-on device recall on predicate device recall with a sibling-pair sample with a single predicate. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). We further require both treated and control devices to have a single predicate device and also require their predicate device to have a single predicate device. The sample consists of 12,957 device-year observations for 1,559 medical devices cleared by 510(k) (1,000 firms) for the sample period from 2002 to 2021. The dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall except for column (2). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we use the linear probability model regressions of *Follow-on Device Recall at* T_0 on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall			
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression
Independent Variable	(1)	(2)	(3)	(4)
Predicate Device Recall	0.170***	0.140***	0.121***	2.317***
	(0.029)	(0.025)	(0.034)	(0.284)
Log(1+Age)	0.003	-0.022***	-0.004	0.247
	(0.004)	(0.008)	(0.005)	(0.342)
Log(1+Number 510K Devices by Firm)	-0.009	-0.020	-0.005	-0.480
	(0.005)	(0.014)	(0.007)	(0.471)
Log(1+Number of Devices in Product Code)	-0.002	-0.015		0.236
	(0.011)	(0.027)		(0.788)
Log(1+Number of New Devices in Product Code)	-0.003	-0.006		-0.003
	(0.003)	(0.005)		(0.332)
Log(1+Ave. Number of Predicates by Product Code)	0.004	0.008		0.157
	(0.006)	(0.008)		(0.371)
Year Fixed Effects	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No
Observations	12,957	12,957	11,488	1,317
Adjusted R-squared	0.126	0.319	0.179	0.187

Table IA10. Recall Propensity of Follow-on Devices after Predicate Device Recall using the Sibling-pair Sample: Including Sibling-pair Fixed Effects

This table reports results from the regressions of follow-on device recall on predicate device recall with sibling-pair fixed effects. We use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). We further restrict the sibling-pair sample to include at least one treated and one control device. The sample consists of 63,870 device-year observations for 3,625 medical devices cleared by 510(k) (1,836 firms) for the sample period from 2002 to 2021. The dependent variable is *Follow-on Device Recall at T_0* at the event year of predicate recall except for columns (2), (5), and (6). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we use the linear probability model regressions of *Follow-on Device Recall at T_0* on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at $T_{[0,+2]}$* that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year in all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*). In all columns, we control for year fixed effects, device fixed effects, and sibling-pair fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall					
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)
Predicate Device Recall	0.073***	0.070***	0.060***	1.534***		
	(0.016)	(0.019)	(0.022)	(0.247)		
Number of Predicate Device Recalls					0.052***	
					(0.014)	
Ratio of Predicate Device Recall						0.156***
						(0.030)
Log(1+Age)	0.011***	-0.002	0.010**	0.916***	0.011***	0.012***
	(0.004)	(0.008)	(0.004)	(0.238)	(0.004)	(0.004)
Log(1+Number 510K Devices by Firm)	-0.001	0.011	0.001	-0.162	-0.002	-0.002
	(0.005)	(0.013)	(0.006)	(0.264)	(0.005)	(0.005)
Log(1+Number of Devices in Product Code)	-0.003	-0.017		-0.213	-0.003	-0.004
	(0.007)	(0.015)		(0.487)	(0.007)	(0.007)
Log(1+Number of New Devices in Product Code)	0.003	-0.003		0.395*	0.003	0.003
	(0.003)	(0.005)		(0.231)	(0.003)	(0.003)
Log(1+Ave. Number of Predicates by Product Code)	-0.003	-0.004		-0.026	-0.003	-0.003
	(0.006)	(0.009)		(0.327)	(0.006)	(0.006)

Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Sibling-pair Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No
Observations	63,870	63,870	62,951	8,586	63,870	63,870
Adjusted R-squared	0.135	0.320	0.236	0.138	0.134	0.139

Table IA11. Recall Propensity of Follow-on Device after Predicate Device Recall using Sibling-pair Sample: Controlling for Manufacturer Quality

This table reports results from the regressions of follow-on device recall on predicate device recall with an additional control for a manufacturer's recall ratio in the previous three years. In columns (1)-(6), we use the sibling-pair sample where we match a treatment device-year observation that experiences a predicate device recall to a control device-year observation that does not experience a predicate device recall while the treated and control devices share an identical non-recalled predicate device in their 2nd upper predicate device (a predicate's predicate). The sample consists of 111,144 device-year observations for 12,619 medical devices cleared by 510(k) (4,865 firms) for the sample period from 2002 to 2021. In column (7), we use the full sample (before sibling matching) that consists of 388,335 device-year observations for 43,623 medical devices cleared by 510(k). In all columns except for column (4), the linear probability model regression is used. The dependent variable is *Follow-on Device Recall at* T_0 at the event year of predicate recall except for columns (2), (5), and (6). The key independent variable is *Predicate Device Recall* that is one if the follow-on device's predicate is recalled in a given year and zero otherwise. In column (1), we regress *Follow-on Device Recall at* T_0 on *Predicate Device Recall*. In column (2), we use *Follow-on Device Recall at* $T_{[0,+2]}$ that is one if a follow-on device is recalled during the three years since the predicate recall and zero otherwise. In column (3), we additionally control for the Product Code x Year Fixed Effects. In column (4), we use a Poisson regression model instead of a linear probability model. In column (5), we use the total number of predicate recalls as the main independent variable. In column (6), we use the fraction of recalled predicate devices in a given year to all predicate devices of a follow-on device (*Ratio of Predicate Device Recall*) as the main independent variable. In column (7), we reestimate the regression in column (1) using the full sample. In all columns, we control for year fixed effects and device fixed effects. Appendix A provides detailed variable descriptions. Standard errors reported in parentheses are robust and clustered by product code. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Dependent Variable: Follow-on Device Recall						
	Follow-on Device Recall at T_0	Follow-on Device Recall at $T_{[0,+2]}$	Controlling for Product Code x Year Fixed Effects	Poisson regression	Using Number of Predicate Recalls	Using Ratio of Predicate Recalls	Full Sample
Independent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Predicate Device Recall	0.103***	0.089***	0.086***	1.632***			0.106***
	(0.012)	(0.010)	(0.010)	(0.110)			(0.007)
Number of Predicate Device Recalls					0.062***		
					(0.005)		
Ratio of Predicate Device Recall						0.192***	
						(0.023)	
Recall Ratio of Firm in Prev 3yrs	-0.102***	-0.330***	-0.116***	-1.550***	-0.105***	-0.100***	-0.094***
	(0.028)	(0.059)	(0.032)	(0.429)	(0.029)	(0.028)	(0.023)
Log(1+Age)	0.008***	-0.004	0.007***	0.745***	0.007***	0.008***	0.010***
	(0.003)	(0.004)	(0.003)	(0.150)	(0.002)	(0.003)	(0.002)
Log(1+Number 510K Devices by Firm)	-0.005*	-0.009	-0.005*	-0.164	-0.004*	-0.005*	-0.008***
	(0.003)	(0.006)	(0.003)	(0.163)	(0.002)	(0.003)	(0.002)
Log(1+Number of Devices in Product Code)	-0.008**	-0.019**		-0.516**	-0.008**	-0.008**	-0.003

	(0.004)	(0.008)		(0.258)	(0.003)	(0.004)	(0.002)
Log(1+Number of New Devices in Product Code)	-0.002	-0.006*		0.035	-0.001	-0.002	-0.001
	(0.001)	(0.003)		(0.086)	(0.001)	(0.001)	(0.001)
Log(1+Ave. Number of Predicates by Product Code)	-0.001	-0.002		-0.101	-0.001	-0.001	-0.000
	(0.002)	(0.003)		(0.128)	(0.002)	(0.002)	(0.001)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Device Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Product Code x Year Fixed Effects	No	No	Yes	No	No	No	No
Observations	111,144	111,144	109,386	10,510	111,144	111,144	388,335
Adjusted R-squared	0.109	0.262	0.085	0.141	0.065	0.067	0.106