Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

Appendix 1. Data collection and sample construction

Overview of Predicate Information Collection

The FDA does not report which predicates were used in an individual 510(k) submission in an analysis-ready format. Accordingly, we attempted to collect predicate information by applying an automated text extraction algorithm to public evidence summary documents from the FDA website and by contacting medical device manufacturers directly. We received few responses from medical device manufacturers and accordingly relied solely on our automated text extraction algorithm. Details of both of our data collection approaches are described below.

Automated Text Extraction Algorithm

We used the FDA's downloadable 510(k) clearance database to identify all 510(k) medical devices cleared between 2003 and 2018.[1] All 510(k) devices cleared during the sample period were required to post either a "statement" file or a public evidence summary to the FDA website. A 510(k) statement file "is a certification that the 510(k) owner will provide safety and effectiveness information supporting the FDA finding of substantial equivalence to ANY person within 30 days of a written request."[2] 510(k) statement files will include the contact information for a manufacturer representative who is assigned to provide information regarding the 510(k) submission. 510(k) statement files typically do not include information on the predicates used in a substantial equivalence determination. As such, we did not apply our automated text extraction algorithm to devices with statement files.

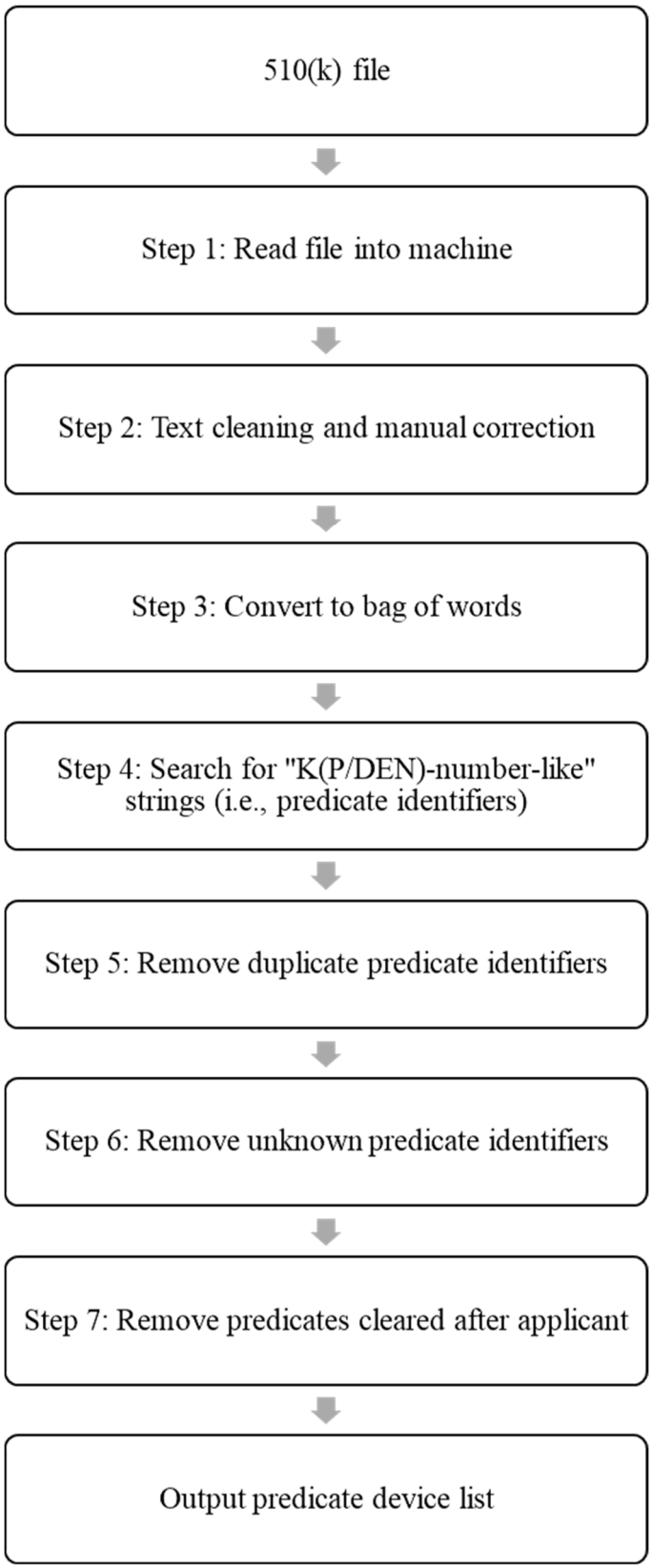
If a manufacturer does not include a statement file, the manufacturer will post a public evidence summary, which will include, "a summary of information upon which [the manufacturer] based [their] claim of substantial equivalence".[2] We applied our automated text extraction algorithm to all 510(k) medical devices with a public evidence summary available on the FDA website.

Our automated text extraction proceeded in seven steps for each 510(k) device (Figure A1):

1. We read the 510(k) pubic evidence summary PDF file into Python. For documents formatted as images of typed, handwritten, or printed text, we used optical character recognition (OCR) tools to convert documents into machine readable text.
2. We performed standard text cleaning for the document, including removing special characters, removing punctuation, and converting all text to lower case. We also manually corrected characters commonly misrecognized by OCR from letters to numbers (e.g., "j" to "1", "o" to "0").
3. We converted the text in the document to a "bag of words", meaning an unstructured set where each word/string in the document is an element in the set.
4. From the bag of words, we identified all words/strings with the format "K######", "P######", and "DEN######", the format of FDA medical device clearance and approval identifiers for 510(k), Premarket Approval (PMA), and De Novo pathways respectively. We output these words/strings to construct the initial predicate device list (PDL).

5. From the PDL, we removed all duplicate K(P/DEN) numbers and all instances in which the K(P/DEN) number matched the K(P/DEN) for the applicant device.
6. From the remaining predicates in the PDL after Step 5, we removed K(P/DEN) numbers where the K(P/DEN) number did not match to any known devices in the FDA database.
7. From the remaining predicates in the PDL after Step 6, we removed K(P/DEN) numbers that matched devices that were cleared or approved by the FDA after the applicant device.

eFigure 1. Flow diagram of automated text extraction steps



Validation of Automated Text Extraction

To assess the accuracy of our automated text extraction algorithm, we manually searched for the predicates cited in a simple random sample of 1,800 public evidence summaries cleared between 2003 and 2012. Searches were performed by research assistants and confirmed by a reviewer (AE).

We compared which predicates were identified in a manual search to the predicates identified using our automated text extraction algorithm (Table A1). We manually identified at least one predicate in 1,784 summary documents (meaning 16 documents did not list an identifiable predicates and thus predicate characteristics were unidentifiable). Our algorithm identified at least one predicate in 1,787 were listed (meaning the algorithm erroneously identified predicates when none were listed). Our algorithm identified the exact same predicates as the manual search (meaning no additional predicates and no missing predicates) in 1,651 cases (91.72%). Our algorithm identified all of the predicates identified in the manual search (i.e., sensitivity, or no missing predicates) in 1,705 cases (94.72%). Our algorithm did not identify additional predicates beyond the predicates identified in the manual search (i.e., specificity) in 1,727 cases (95.94%).

We also compared the features of the predicates identified in our text extraction algorithm to the features of predicates identified through our manual search. For each studied predicate characteristics, we calculated sample means or proportions as appropriate and corresponding 95% confidence intervals. All 95% confidence intervals between the manually coded sample and the automated text extraction sample overlapped for all studied predicate characteristics (Table A2).

We could not calculate predicate features for devices where we could not identify at least one of its predicates. We could not identify predicates in instances where predicates were listed by name only (meaning predicates could not be reliably linked to the FDA's clearance and approval databases), predicates' identifier numbers were listed incorrectly in the summary document, predicates were not listed in the summary document at all, or predicates were missed due to OCR errors in our text extraction algorithm. Since predicates that entered the market prior to the FDA's 1976 authority to regulate medical devices do not have an FDA device identifier assigned to them, both our manual search and our automated text extraction algorithm were unable to identify predicates that came to market before 1976.

eTable 1. Accuracy of automated text extraction algorithm

Algorithm identified predicates are exact match to manually identified predicates	N	1,651
	%	91.72%
Algorithm identified all predicates identified in manual search	N	1,705
	%	94.72%
Algorithm did not identify predicates not identified in manual search	N	1,727
	%	95.94%
Total devices considered	N	1,800
	%	100.00%

eTable 2. Comparison of predicate characteristics between predicates identified via text extraction and predicates identified via manual search

		Text extraction-generated file	Manually coded file
N		1,787	1,784
Mean predicate age (years)	Mean	4.88	4.94
	95% CI	(4.69, 5.07)	(4.76, 5.13)
Newest predicate age (years)	Mean	3.44	3.46
	95% CI	(3.26, 3.62)	(3.28, 3.63)
Oldest predicate age (years)	Mean	6.69	6.71
	95% CI	(6.44, 6.95)	(6.46, 6.97)
Number of predicates cited	Mean	2.46	2.46
	95% CI	(2.35, 2.57)	(2.35, 2.58)
Number of unique non-concordant predicate product codes	Mean	0.18	0.15
	95% CI	(0.16, 0.20)	(0.13, 0.17)
Number of unique non-concordant predicate advisory committees	Mean	0.63	0.61
	95% CI	(0.59, 0.68)	(0.57, 0.65)
At least one predicate received FDA clearance 10 years or more prior to applicant FDA clearance	%	21.60%	21.75%
	95% CI	(19.75%, 23.57%)	(19.89%, 23.73%)
At least one ongoing predicate recall at time of FDA decision for applicant device	%	2.52%	2.52%
	95% CI	(1.88%, 3.36%)	(1.89%, 3.36%)

Notes: Predicate age defined as number of years between clearance of predicate device and clearance of applicant device. “Ongoing” predicate recalls defined as Class I or Class II recalls classified by the FDA but not yet terminated at time of clearance for applicant device.

Requesting Predicate Information from Manufacturers

In instances where manufacturers did not post a public evidence summary to the FDA website, we used the contact information in the manufacturer's "statement" file to send the manufacturer a letter requesting information about the predicates cited in their 510(k) submission. Of the 49,960 devices cleared between 2003 and 2019, there were a total of 5,588 devices for which a public evidence summary was unavailable. Between August 10th, 2020, and August 17th, 2020, we sent 2,060 letters to manufacturers in the U.S. and 930 letters to manufacturers outside of the U.S. requesting information on predicates cited in 510(k) submissions (many letters requested information on predicates for multiple medical devices). We received responses from 290 manufacturers. Given the overall low response rate and likely non-random decision to respond to the request, we excluded all devices from our sample where a public evidence summary was unavailable.

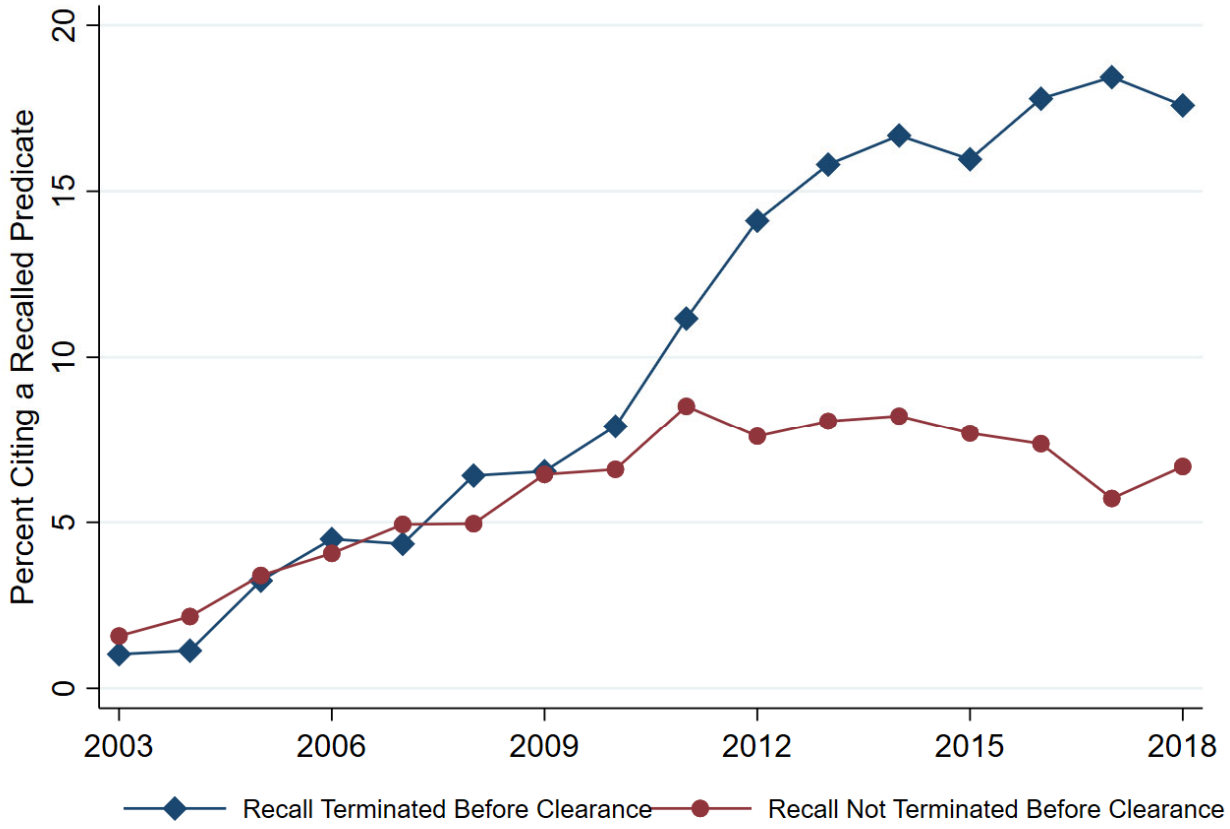
Identification of On-going Predicate Recalls

The FDA does not consistently report medical device recalls initiated before 2002.[3] As such, when constructing a measure of predicate recall status, we only considered Class I/II predicate recalls that were classified by the FDA (meaning initiated by the manufacturer and assigned to a recall class by the FDA) prior to the clearance of the applicant device and either terminated after the clearance of the applicant device or not terminated as of December 31, 2020 (or "ongoing" predicate recalls). Including predicate recalls terminated prior to the clearance of the applicant device in our measure of predicate recall status would have disproportionately undercounted predicate recalls among applicant devices cleared earlier in our sample.

For example, suppose Device A is cleared in 2003 and Device B is cleared in 2010. Both Devices A and B have predicates that were recalled, with those recalls initiated and terminated five years prior to Device A and B's regulatory clearances. We would be able to observe the terminated predicate recall for Device B, as the predicate recall occurred in 2005, but we could not observe the terminated predicate recall for Device A, as the predicate recall occurred in 1998 (a year in which we do not have recall data).

Empirically, we observe temporal changes in the proportion of devices citing predicates with observable terminated recalls and ongoing recalls consistent with this expected pattern of missingness. The proportion of devices citing a predicate with a recall terminated prior to clearance of the applicant device increased over the entire sample period (consistent with decreasing missingness over time). In contrast, the proportion of devices of citing a predicate with a recall either terminated after the clearance of the applicant device or not terminated as of December 31, 2020 is relatively constant over the sample period (Figure A2).

eFigure 2. Mean predicate recalls by date of recall termination relative to applicant device clearance



Note: Authors' analysis of 510(k) medical devices cleared by the FDA between 2003 and 2018. Predicate recalls defined as either Class I or II recalls initiated and terminated prior to FDA clearance of the applicant device ("Recall Terminated Before Clearance") or Class I/II recalls classified by the FDA prior to FDA clearance of the applicant device but terminated after FDA clearance of the applicant device or not terminated as of December 31, 2020 ("Recall Not Terminated Before Clearance"). Annual proportions of devices citing at least one recalled predicate are plotted.

Identification of Predicate Recall Cause

The FDA attributes recalls to a discrete number of recall causes. Example causes include "Device Design", "Material/Component Contamination", and "Software Design." In order to facilitate more tractable analyses by cause of predicate recall, we manually assigned all Class I and II recalls that occurred during our sample period to one of eight recall cause categories. Recall cause categories and number and percent of all recall causes assigned to each category are reported in Table A3.

Assignment of Manufacturer

The FDA does not assign a unique identifier to manufacturers. As such, a manufacturer may appear in the FDA's 510(k) with multiple distinct names. For example, Boston Scientific appears as: "BOSTON SCIENTIFIC", "Boston Scientific", "BOSTON SCIENTIFIC – PRECISION VASCULAR", "BOSTON SCIENTIFIC CORP.", "Boston Scientific Corporation", "BOSTON SCIENTIFIC CORPORATION", "BOSTON SCIENTIFIC EP TECHNOLOGIES", and "BOSTON SCIENTIFIC IVT". We manually assigned similar manufacturers to a single manufacturer name for all analyses.

Sample Construction

Construction of our analytic sample proceeded in six steps (Figure A3). First, we identified all 510(k) medical devices cleared by the FDA between 2003 and 2018 (n = 48,747). Second, we removed all observations without a public evidence summary available on the FDA website (n = 44,386). Third, we removed all devices where a predicate could not be identified with our automated text extraction algorithm (n = 44,334). Fourth, after removing all predicates where the listed predicate identifier did not link to the FDA database, we removed all devices without a predicate (n = 40,175). Fifth, after removing all predicates that were cleared after the applicant device (something that should be impossible and only a result of an error either in text extraction or the manufacturer's documentation), we removed all devices without a predicate (n = 40,138). Sixth, we removed all "singleton" observations where only one observation exists within a year, manufacturer, or product type group in order to facilitate fixed effects analyses (see details on fixed effects in Appendix B) (n = 35,176). Among our final sample, 4,007 devices experienced a Class I or Class II recall between its regulatory clearance and December 31, 2020, while 31,169 did not (Figure A3).

eTable 3. Manual assignment of FDA recall cause problem categories

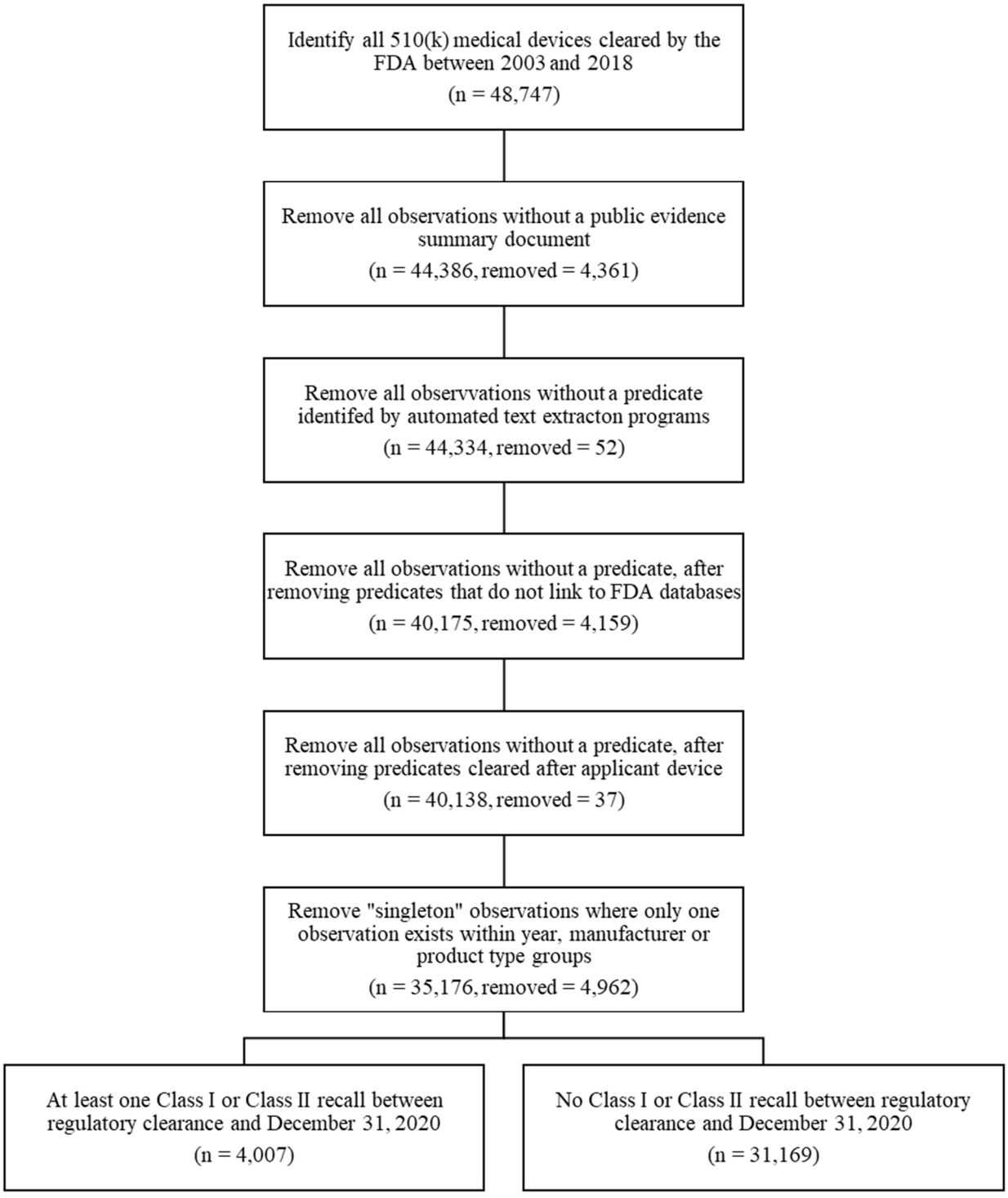
			Recall Category							
FDA Determined Cause of Recall	**Number of Recalls**	**Percent of Total Recalls**	*Component or Device Design*	*Labeling*	*Materials or Composition*	*Application*	*Packaging*	*Software*	*Manufacturing Environment*	*Miscellaneous*
Component change control	146	0.86%	X							
Component design/selection	480	2.82%	X							
Counterfeit	4	0.02%								X
Device Design	2125	12.47%	X							
Employee error	509	2.99%								X
Environmental control	32	0.19%							X	
Equipment maintenance	139	0.82%							X	
Error in labeling	308	1.81%		X						
Finished device change control	27	0.16%	X							
Incorrect or no expiration date	61	0.36%		X						
Labeling Change Control	177	1.04%		X						
Labeling False and Misleading	150	0.88%		X						
Labeling design	224	1.31%		X						
Labeling mix-ups	354	2.08%		X						
Manufacturing material removal	33	0.19%			X					
Material/Component Contamination	179	1.05%			X					
Mixed-up of materials/components	216	1.27%			X					
No Marketing Application	122	0.72%				X				
Nonconforming Material/Component	1568	9.20%			X					

			Recall Category							
FDA Determined Cause of Recall	**Number of Recalls**	**Percent of Total Recalls**	*Component or Device Design*	*Labeling*	*Materials or Composition*	*Application*	*Packaging*	*Software*	*Manufacturing Environment*	*Miscellaneous*
Other	3536	20.75%								X
PMA	45	0.26%				X				
Packaging	209	1.23%					X			
Packaging change control	50	0.29%					X			
Packaging process control	346	2.03%					X			
Package design/selection	135	0.79%					X			
Pending	92	0.54%								X
Process change control	156	0.92%							X	
Process control	1546	9.07%							X	
Process design	343	2.01%							X	
Radiation Control for Health and Safety Act	167	0.98%								X
Release of Material/Component prior to receiving test results	37	0.22%				X				
Reprocessing Controls	21	0.12%							X	
Software Design Change	77	0.45%						X		
Software Manufacturing/Software Deployment	59	0.35%						X		
Software change control	94	0.55%						X		
Software design	1751	10.27%						X		
Software design (manufacturing process)	68	0.40%						X		
Software in the Use Environment	51	0.30%						X		
Storage	25	0.15%							X	

			Recall Category							
FDA Determined Cause of Recall	**Number of Recalls**	**Percent of Total Recalls**	*Component or Device Design*	*Labeling*	*Materials or Composition*	*Application*	*Packaging*	*Software*	*Manufacturing Environment*	*Miscellaneous*
Under Investigation by firm	1053	6.18%								X
Unknown/Undetermined by firm	153	0.90%								X
Use error	114	0.67%								X
Vendor change control	56	0.33%							X	
pec">	5	0.03%								X
Total	**17043**	**100.00%**								

eFigure 3. Sample construction steps

See next page for figure



eAppendix 2. Statistical analysis and additional results

Primary Specification: Linear Probability Models

All regression modeling presented in the main manuscript uses linear probability model to predict whether a 510(k) device experienced a Class I or Class II recall as a function of predicate characteristics, manufacturer experience, and time, manufacturer, and product type fixed effects (indicator variables) in a cross-sectional sample of 510(k) medical devices cleared between 2003 and 2018:

$$Recall_i = \beta_0 + \beta_i * PredicateChar_i + \beta_k * FirmExperience_{k,t} + \alpha_j + \gamma_k + \delta_t + \varepsilon_i$$

where *i* denotes an individual medical device (the unit of observation), *j* denotes the product type of the device (as identified in the FDA Product Classification database), *k* denotes the manufacturer of device *i*, and *t* denotes the year device *i* received regulatory clearance from the FDA. Results from our main specification are presented in Table 2 in the main manuscript. To test the extent of potential multicollinearity among our studied predicate characteristics, we calculate variance inflation factors for individual covariates and the condition number for the set of covariates (Table B1). We find variance inflation factors less than 2.5 and a condition number less than 10, satisfying conventional thresholds for acceptable multicollinearity.[4–6]

Results with based on separate models for each medical specialty are presented in Table 3 in the main manuscript and in Tables B2 (without fixed effects adjustments) and B3 (with fixed effects adjustments). Results with more granular predicate characteristics, reporting predicate recalls by recall cause, are reported in Table 4 in the main manuscript.

All standard errors were clustered at the manufacturer level, given that manufacturers decide which devices they cite in 510(k) submissions (i.e., manufacturers "assign treatment").[7] Estimating fixed effects in groups with only a single observation in a group ("singletons") can lead to underestimated standard errors and overestimated statistical significance.[8] Accordingly, we remove all "singleton" observations from our analyses.

We included manufacturer and product type fixed effects to account for time-invariant differences in recall probabilities across manufacturers and product types. Some manufacturers may have preferences for using certain types of predicates in 510(k) submissions (e.g., older predicates), and these preferences may be spuriously correlated with the safety of products developed by the manufacturer. If unobserved predicate preferences are correlated with the safety of a manufacturer's products, estimates of the relationship between predicate characteristics and recall probability would be biased in the absence of manufacturer fixed effects. Similarly, some medical device product types likely have differences in their underlying safety profile, and these safety differences may be spuriously correlated with predicate citation patterns within certain product types. Including product type fixed effects allowed us control for unobserved time-invariant differences between product types and examine how recall risk varied by predicate characteristics within the same product type (e.g., a semi-constrained cemented metal/polymer hip prosthesis that cites a predicate with an ongoing recall vs a semi-constrained cemented metal/polymer hip prosthesis does not cite predicate with an ongoing recall).

Prior work has demonstrated that non-linear models (e.g., logistic models, Cox proportional hazard models) may estimate biased fixed effects when the number of observations per group is small (with "small" typically defined as fewer than 16 observations), commonly known as the "incidental parameters problem".[9–11] Given this limitation of non-linear models, we used linear probability models in our main specifications.

eTable 4. Condition number and variance inflation factors for predicate characteristics of interest

Condition Number	5.67
Variance Inflation Factors	
Age of Newest Predicate (Years)	1.80
Age of Oldest Predicate (Years)	1.94
Number of Predicates	1.84
Number of Unique Non-matching Predicate Product Types	2.11
Number of Unique Non-matching Predicate Medical Specialties	1.44
Number of Ongoinge Class I or Class II Predicate Recalls	
1	1.01
2	1.01
≥3	1.01
Number of Prior 510(k) Clearances from Manufacturer	1.31
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	1.33

eTable 5. Change in unadjusted probability of class I or II recalls of 510(k) medical devices for different medical specialties by predicate characteristics

Adjustment for product type[a] and manufacturer fixed effects[b]	Unadjusted	Unadjusted	Unadjusted	Unadjusted	Unadjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Anesthesiology	Clinical Chemistry	Cardiovascular	Dental	Ear, Nose, & Throat
N	1,596	1,659	4,440	2,294	334
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall[e] per Unit Change in Predicate Characteristic (95% CI)**				
Age of Newest Predicate (Years)	-0.18 (-0.70, 0.34)	-0.69 (-1.37, -0.01)	-0.51 (-0.82, -0.21)	-0.18 (-0.41, 0.04)	-0.35 (-1.13, 0.43)
Age of Oldest Predicate (Years)	0.03 (-0.51, 0.57)	0.38 (-0.26, 1.01)	0.29 (0.04, 0.55)	0.12 (-0.04, 0.28)	0.23 (-0.43, 0.89)
Number of Predicates	1.13 (-0.21, 2.47)	1.25 (-2.00, 4.50)	0.53 (-0.30, 1.35)	0.36 (-0.10, 0.82)	-1.07 (-2.77, 0.64)
Number of Unique Non-matching Predicate Product Types[f]	-3.65 (-8.63, 1.34)	0.42 (-5.42, 6.25)	-1.81 (-4.60, 0.98)	1.88 (-0.79, 4.54)	8.46 (-0.02, 16.93)
Number of Unique Non-matching Predicate Medical Specialties[g]	3.21 (-1.00, 7.42)	0.52 (-2.18, 3.21)	-0.56 (-2.67, 1.55)	-1.52 (-3.14, 0.10)	0.12 (-4.26, 4.50)
Number of Ongoing[h] Class I or Class II Predicate Recalls					
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	24.76 (12.84, 36.69)	10.21 (1.58, 18.85)	12.30 (4.45, 20.15)	4.92 (-2.27, 12.12)	3.55 (-23.73, 30.83)
2	22.56 (6.32, 38.81)	18.11 (-5.99, 42.22)	23.45 (12.85, 34.05)	42.51 (-27.82, 112.85)	61.96 (5.51, 118.41)
≥3	22.56 (-1.21, 46.33)	26.36 (0.48, 52.24)	21.27 (7.13, 35.41)	-5.78 (-10.15, -1.42)	N/A
Number of Prior 510(k) Clearances from Manufacturer	0.05 (-0.02, 0.12)	0.04 (0.03, 0.05)	0.02 (0.01, 0.04)	0.02 (-0.01, 0.04)	0.02 (0.00, 0.03)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	-0.11 (-0.29, 0.08)	-0.41 (-0.67, -0.14)	0.09 (-0.15, 0.32)	0.05 (-0.10, 0.20)	-0.08 (-0.58, 0.42)

Adjustment for product type[a] and manufacturer fixed effects[b]	Unadjusted	Unadjusted	Unadjusted	Unadjusted	Unadjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Gastroenterology and Urology	Hematology	General Hospital	Immunology	Microbiology
N	1,626	336	2,363	301	720
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall[e] per Unit Change in Predicate Characteristic (95% CI)**				
Age of Newest Predicate (Years)	-0.32 (-0.68, 0.05)	0.41 (-0.34, 1.16)	-0.25 (-0.64, 0.14)	-1.16 (-2.05, -0.28)	-1.17 (-1.82, -0.53)
Age of Oldest Predicate (Years)	0.27 (-0.07, 0.61)	-0.77 (-1.54, 0.00)	-0.04 (-0.33, 0.25)	0.81 (-0.25, 1.87)	0.59 (-0.06, 1.23)
Number of Predicates	-0.48 (-1.64, 0.67)	5.24 (0.30, 10.18)	2.13 (0.52, 3.74)	1.08 (-4.98, 7.14)	-0.21 (-0.53, 0.12)
Number of Unique Non-matching Predicate Product Types[f]	3.84 (-1.12, 8.80)	-4.83 (-18.56, 8.90)	-0.77 (-6.71, 5.17)	4.28 (-0.30, 8.87)	1.39 (-4.54, 7.32)
Number of Unique Non-matching Predicate Medical Specialties[g]	-1.03 (-3.64, 1.58)	-6.15 (-13.51, 1.21)	-1.61 (-6.18, 2.97)	-8.30 (-14.79, -1.81)	-0.31 (-5.04, 4.43)
Number of Ongoing[h] Class I or Class II Predicate Recalls					
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	22.72 (11.31, 34.13)	9.34 (-5.19, 23.87)	8.27 (0.17, 16.38)	17.09 (-22.36, 56.54)	-3.90 (-16.29, 8.50)
2	14.35 (-6.83, 35.54)	43.94 (1.53, 86.34)	4.76 (-9.13, 18.64)	-22.07 (-38.61, -5.52)	10.28 (-21.37, 41.94)
≥3	59.54 (32.20, 86.89)	26.42 (-39.36, 92.20)	36.29 (15.66, 56.93)	24.54 (2.89, 46.19)	-3.94 (-11.77, 3.88)
Number of Prior 510(k) Clearances from Manufacturer	-0.01 (-0.03, 0.01)	0.02 (-0.03, 0.06)	0.03 (0.00, 0.07)	-0.02 (-0.05, 0.01)	0.01 (-0.02, 0.04)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	1.11 (0.03, 2.20)	0.77 (-0.48, 2.02)	0.10 (-0.32, 0.52)	-0.69 (-1.13, -0.25)	-0.10 (-0.16, -0.04)

Adjustment for product type[a] and manufacturer fixed effects[b]	Unadjusted	Unadjusted	Unadjusted	Unadjusted	Unadjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Neurology	Obstetrics/ Gynecology	Opthalmic	Orthopedic	Pathology
N	1,274	613	675	6,696	53
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall[e] per Unit Change in Predicate Characteristic (95% CI)**				
Age of Newest Predicate (Years)	-0.03 (-0.52, 0.45)	0.05 (-0.35, 0.45)	-0.20 (-0.64, 0.23)	0.07 (-0.24, 0.38)	6.17 (-1.58, 13.93)
Age of Oldest Predicate (Years)	0.14 (-0.22, 0.49)	-0.26 (-0.64, 0.11)	-0.33 (-0.72, 0.05)	0.19 (-0.07, 0.45)	-3.22 (-9.79, 3.36)
Number of Predicates	0.76 (-0.46, 1.98)	1.18 (-1.78, 4.15)	1.03 (-1.35, 3.42)	0.30 (-0.10, 0.70)	7.42 (-9.96, 24.81)
Number of Unique Non-matching Predicate Product Types[f]	0.83 (-2.90, 4.55)	1.67 (-4.44, 7.77)	4.81 (-3.59, 13.20)	0.41 (-1.60, 2.43)	6.91 (-38.40, 52.23)
Number of Unique Non-matching Predicate Medical Specialties[g]	-1.99 (-4.47, 0.48)	-0.49 (-5.73, 4.75)	-1.65 (-6.12, 2.83)	0.39 (-0.50, 1.29)	-11.51 (-27.46, 4.45)
Number of Ongoing[h] Class I or Class II Predicate Recalls					
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	-0.14 (-13.62, 13.33)	-6.94 (-12.81, -1.06)	15.75 (2.13, 29.37)	2.25 (-1.51, 6.02)	36.25 (13.13, 59.36)
2	15.24 (-33.63, 64.11)	-11.17 (-20.31, -2.03)	49.01 (13.81, 84.21)	6.76 (-2.67, 16.20)	N/A
≥3	23.08 (-36.91, 83.08)	-15.02 (-27.97, -2.07)	-3.76 (-11.88, 4.35)	25.44 (0.81, 50.07)	N/A
Number of Prior 510(k) Clearances from Manufacturer	0.04 (0.03, 0.06)	0.03 (-0.01, 0.07)	0.13 (0.03, 0.22)	0.02 (-0.01, 0.05)	-1.24 (-3.64, 1.15)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	0.83 (0.33, 1.34)	-0.69 (-1.14, -0.24)	-0.48 (-1.56, 0.61)	-0.20 (-0.33, -0.06)	10.78 (4.13, 17.42)

Adjustment for product type[a] and manufacturer fixed effects[b]	Unadjusted	Unadjusted	Unadjusted	Unadjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Physicial Medicine	Radiology	General & Plastic Surgery	Clinical Toxocology
N	540	4,368	3,645	275
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall per Unit in Pred. Char. (95% CI)**			
Age of Newest Predicate (Years)	0.13 (-0.30, 0.57)	-0.45 (-0.98, 0.08)	0.14 (-0.18, 0.46)	-0.80 (-2.53, 0.92)
Age of Oldest Predicate (Years)	-0.05 (-0.35, 0.26)	-0.21 (-0.53, 0.11)	-0.08 (-0.27, 0.11)	1.31 (-0.19, 2.82)
Number of Predicates	1.42 (-0.68, 3.53)	0.92 (-0.10, 1.95)	-0.04 (-0.62, 0.53)	3.05 (-1.22, 7.32)
Number of Unique Non-matching Predicate Product Types[f]	-0.39 (-2.69, 1.90)	-0.64 (-5.07, 3.79)	-0.27 (-3.18, 2.65)	-3.31 (-8.66, 2.04)
Number of Unique Non-matching Predicate Medical Specialties[g]	-3.66 (-7.04, -0.28)	-1.08 (-2.96, 0.81)	-0.32 (-2.77, 2.12)	-2.40 (-7.14, 2.34)
Number of Ongoing[h] Class I or Class II Predicate Recalls				
0	Reference Group	Reference Group	Reference Group	Reference Group
1	-3.49 (-8.23, 1.26)	14.08 (8.33, 19.83)	7.71 (1.90, 13.53)	22.10 (-14.17, 58.38)
2	47.39 (-16.96, 111.75)	16.31 (6.68, 25.94)	4.72 (-10.36, 19.79)	42.23 (-27.94, 112.40)
≥3	N/A	26.58 (14.99, 38.16)	22.50 (9.60, 35.40)	89.20 (73.88, 104.51)
Number of Prior 510(k) Clearances from Manufacturer	0.08 (-0.11, 0.28)	0.05 (0.04, 0.07)	0.02 (0.00, 0.04)	0.00 (-0.02, 0.01)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	0.31 (-0.47, 1.08)	-0.21 (-0.37, -0.04)	0.17 (-0.02, 0.37)	-0.83 (-2.41, 0.75)

a. “Product types” are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
b. Variations on similar manufacturer names present in FDA databases are standardized into a single manufacturer name. See Appendix A for details.
c. Predicate age defined as number of years between clearance of predicate device and clearance of applicant device.
d. Medical specialty refers to 1 of the 19 FDA medical specialty review panels that are responsible for reviewing a medical device. Medial specialty review panels are assigned based on a medical device’s product type.
e. Linear probability models were used to model change in probability of applicant device experiencing a Class I or Class II recall between its regulatory clearance and December 31, 2020 per unit change in characteristics of the device’s predicates. Recalls are classified as Class I when there is potential for serious patient harm or death and Class II when there is potential for temporary or reversible patient harm or a slight chance of serious patient harm or death. Models adjust for

listed predicate and manufacturer characteristics, year fixed effects, and product type and manufacturer fixed effects when indicated. All standard errors are clustered at the manufacturer level.
f. “Non-matching predicate product types” refer to number of unique predicate product types that do not match product type of applicant device. Product types are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
g. “Non-matching predicate specialties” refer to number of unique predicate medical specialties that do not match specialty of applicant device.
h. “Ongoing” predicate recalls defined as Class I or Class II recalls classified by the FDA but not yet terminated at time of clearance for applicant device.

eTable 6. Change in adjusted probability of class I/II recalls of 510(k) medical devices for different medical specialties by predicate characteristics

Adjustment for product type[a] and manufacturer fixed effects[b]	Adjusted	Adjusted	Adjusted	Adjusted	Adjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Anesthesiology	Clinical Chemistry	Cardiovascular	Dental	Ear, Nose, & Throat
N	1,596	1,659	4,440	2,294	334
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall[e] per Unit Change in Predicate Characteristic (95% CI)**				
Age of Newest Predicate (Years)	-0.21 (-0.87, 0.44)	-0.54 (-1.32, 0.23)	-0.55 (-0.86, -0.23)	-0.07 (-0.29, 0.15)	0.37 (-0.73, 1.47)
Age of Oldest Predicate (Years)	0.13 (-0.56, 0.81)	0.14 (-0.53, 0.80)	0.26 (-0.03, 0.54)	0.04 (-0.13, 0.20)	-0.04 (-1.29, 1.21)
Number of Predicates	0.53 (-0.92, 1.99)	0.19 (-2.64, 3.03)	0.60 (-0.15, 1.35)	0.34 (-0.14, 0.82)	0.06 (-2.24, 2.35)
Number of Unique Non-matching Predicate Product Types[f]	0.43 (-4.88, 5.74)	-0.59 (-5.57, 4.38)	-1.51 (-4.40, 1.39)	1.68 (-1.35, 4.72)	10.05 (1.86, 18.24)
Number of Unique Non-matching Predicate Medical Specialties[g]	0.30 (-3.21, 3.82)	2.20 (-0.49, 4.90)	-1.72 (-4.13, 0.68)	-1.46 (-3.33, 0.41)	-3.64 (-11.82, 4.54)
Number of Ongoing[h] Class I or Class II Predicate Recalls					
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	12.92 (1.88, 23.97)	-0.87 (-10.99, 9.26)	0.96 (-6.58, 8.51)	2.21 (-5.97, 10.40)	-4.50 (-32.15, 23.14)
2	3.83 (-10.15, 17.82)	-2.34 (-22.21, 17.52)	7.07 (-5.05, 19.19)	25.89 (-47.87, 99.66)	62.46 (2.23, 122.68)
≥3	10.05 (-14.81, 34.90)	12.77 (-7.48, 33.03)	-5.09 (-14.49, 4.32)	-20.90 (-25.80, -16.00)	N/A
Number of Prior 510(k) Clearances from Manufacturer	0.00 (-0.11, 0.12)	-0.01 (-0.06, 0.03)	0.00 (-0.04, 0.03)	-0.07 (-0.15, 0.00)	-0.07 (-0.19, 0.06)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	0.08 (-0.10, 0.25)	0.08 (-0.09, 0.26)	0.21 (-0.06, 0.48)	-0.03 (-0.19, 0.14)	0.24 (-0.87, 1.36)

Adjustment for product type[a] and manufacturer fixed effects[b]	Adjusted	Adjusted	Adjusted	Adjusted	Adjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Gastroenterology and Urology	Hematology	General Hospital	Immunology	Microbiology
N	1,626	336	2,363	301	720
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall[e] per Unit Change in Predicate Characteristic (95% CI)**				
Age of Newest Predicate (Years)	-0.31 (-0.75, 0.12)	0.59 (-0.43, 1.62)	-0.23 (-0.64, 0.17)	-1.48 (-2.81, -0.14)	-0.80 (-1.67, 0.06)
Age of Oldest Predicate (Years)	0.24 (-0.20, 0.69)	-0.78 (-1.69, 0.13)	0.01 (-0.31, 0.32)	1.02 (-0.40, 2.43)	0.47 (-0.26, 1.19)
Number of Predicates	-0.27 (-1.74, 1.20)	4.00 (-1.01, 9.01)	0.97 (-0.59, 2.54)	0.33 (-5.66, 6.31)	-0.02 (-0.73, 0.69)
Number of Unique Non-matching Predicate Product Types[f]	4.28 (-1.85, 10.41)	-4.72 (-25.64, 16.19)	1.38 (-5.34, 8.10)	-1.24 (-11.97, 9.49)	4.53 (-2.10, 11.15)
Number of Unique Non-matching Predicate Medical Specialties[g]	0.04 (-3.50, 3.58)	-3.16 (-11.27, 4.96)	-3.84 (-7.67, -0.01)	-5.33 (-13.61, 2.96)	-1.14 (-8.34, 6.05)
Number of Ongoing[h] Class I or Class II Predicate Recalls					
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	9.36 (-2.83, 21.55)	-16.41 (-39.89, 7.08)	-8.87 (-16.85, -0.89)	-16.37 (-48.18, 15.45)	9.36 (-2.83, 21.55)
2	-10.87 (-36.85, 15.12)	21.03 (-35.31, 77.36)	-16.56 (-26.65, -6.47)	-15.07 (-74.23, 44.09)	-10.87 (-36.85, 15.12)
≥3	26.18 (-11.93, 64.28)	18.56 (-37.81, 74.93)	9.04 (-17.16, 35.24)	26.42 (-3.32, 56.17)	26.18 (-11.93, 64.28)
Number of Prior 510(k) Clearances from Manufacturer	0.00 (-0.04, 0.04)	0.01 (-0.05, 0.07)	0.05 (0.01, 0.09)	-0.10 (-0.19, -0.01)	0.00 (-0.04, 0.04)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	0.81 (-0.18, 1.79)	-0.96 (-2.82, 0.91)	-0.09 (-0.53, 0.34)	0.22 (-0.48, 0.93)	0.81 (-0.18, 1.79)

Adjustment for product type[a] and manufacturer fixed effects[b]	Adjusted	Adjusted	Adjusted	Adjusted	Adjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Neurology	Obstetrics/ Gynecology	Opthalmic	Orthopedic	Pathology
N	1,274	613	675	6,696	53
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall[e] per Unit Change in Predicate Characteristic (95% CI)**				
Age of Newest Predicate (Years)	0.06 (-0.51, 0.64)	0.05 (-0.54, 0.63)	-0.31 (-0.70, 0.09)	0.00 (-0.33, 0.33)	6.53 (-7.05, 20.11)
Age of Oldest Predicate (Years)	0.08 (-0.42, 0.58)	-0.51 (-1.11, 0.08)	-0.12 (-0.56, 0.32)	0.07 (-0.17, 0.30)	-5.51 (-26.83, 15.80)
Number of Predicates	0.28 (-1.33, 1.88)	1.32 (-2.13, 4.76)	1.23 (-0.85, 3.32)	0.46 (0.12, 0.80)	3.77 (-41.88, 49.41)
Number of Unique Non-matching Predicate Product Types[f]	-2.30 (-6.36, 1.76)	2.56 (-5.31, 10.43)	5.42 (-3.03, 13.87)	0.92 (-1.11, 2.95)	10.17 (-78.42, 98.77)
Number of Unique Non-matching Predicate Medical Specialties[g]	1.45 (-1.65, 4.55)	-0.79 (-7.66, 6.08)	-3.12 (-8.41, 2.17)	0.22 (-0.67, 1.11)	-7.79 (-39.46, 23.88)
Number of Ongoing[h] Class I or Class II Predicate Recalls					
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	-10.84 (-26.91, 5.24)	-19.47 (-35.06, -3.87)	9.00 (-7.03, 25.03)	-1.98 (-5.59, 1.63)	24.46 (-19.88, 68.79)
2	-6.15 (-59.04, 46.73)	-21.02 (-30.96, -11.08)	22.81 (-8.41, 54.03)	1.34 (-8.50, 11.19)	N/A
≥3	-17.00 (-44.44, 10.44)	-21.72 (-39.44, -4.00)	-43.56 (-101.75, 14.63)	17.36 (-8.12, 42.84)	N/A
Number of Prior 510(k) Clearances from Manufacturer	0.02 (-0.03, 0.08)	0.02 (-0.11, 0.15)	-0.36 (-0.90, 0.18)	0.00 (-0.03, 0.02)	-10.89 (-26.44, 4.67)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	1.05 (0.48, 1.63)	0.17 (-0.77, 1.11)	0.21 (-1.54, 1.96)	-0.18 (-0.32, -0.03)	22.54 (-7.39, 52.47)

Adjustment for product type[a] and manufacturer fixed effects[b]	Unadjusted	Unadjusted	Unadjusted	Unadjusted
Definition of predicate age[c]	Oldest and newest age	Oldest and newest age	Oldest and newest age	Oldest and newest age
Medical Specialty[d]	Physicial Medicine	Radiology	General & Plastic Surgery	Clinical Toxocology
N	540	4,368	3,645	275
Predicate Characteristics	**P.p. Change in Prob. of Class I or II Recall per Unit in Pred. Char. (95% CI)**			
Age of Newest Predicate (Years)	-0.24 (-0.87, 0.39)	-0.33 (-0.86, 0.20)	0.08 (-0.33, 0.49)	-0.96 (-2.63, 0.72)
Age of Oldest Predicate (Years)	0.19 (-0.20, 0.57)	-0.15 (-0.55, 0.25)	-0.08 (-0.32, 0.16)	1.43 (-0.03, 2.89)
Number of Predicates	-0.19 (-2.20, 1.82)	1.02 (-0.05, 2.10)	0.19 (-0.68, 1.06)	1.19 (-2.89, 5.27)
Number of Unique Non-matching Predicate Product Types[f]	-2.10 (-7.29, 3.08)	1.65 (-2.06, 5.35)	-1.34 (-4.59, 1.92)	-2.27 (-7.55, 3.01)
Number of Unique Non-matching Predicate Medical Specialties[g]	-1.59 (-5.59, 2.42)	-2.14 (-4.50, 0.21)	-0.17 (-2.96, 2.61)	0.33 (-4.89, 5.54)
Number of Ongoing[h] Class I or Class II Predicate Recalls				
0	Reference Group	Reference Group	Reference Group	Reference Group
1	-11.48 (-30.39, 7.43)	7.19 (1.17, 13.21)	-2.35 (-8.08, 3.38)	0.76 (-31.77, 33.29)
2	34.86 (-11.99, 81.70)	3.13 (-4.24, 10.49)	-6.68 (-21.91, 8.56)	-3.82 (-15.03, 7.40)
≥3	N/A	11.03 (-0.62, 22.68)	8.97 (-11.11, 29.05)	-2.71 (-16.97, 11.54)
Number of Prior 510(k) Clearances from Manufacturer	-0.19 (-0.81, 0.43)	-0.01 (-0.03, 0.01)	-0.04 (-0.09, 0.02)	-0.09 (-0.15, -0.02)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	1.13 (0.14, 2.13)	-0.12 (-0.24, -0.01)	-0.32 (-0.56, -0.07)	0.35 (-1.10, 1.81)

a. “Product types” are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
b. Variations on similar manufacturer names present in FDA databases are standardized into a single manufacturer name. See Appendix A for details.
c. Predicate age defined as number of years between clearance of predicate device and clearance of applicant device.
d. Medical specialty refers to 1 of the 19 FDA medical specialty review panels that are responsible for reviewing a medical device. Medial specialty review panels are assigned based on a medical device’s product type.
e. Linear probability models were used to model change in probability of applicant device experiencing a Class I or Class II recall between its regulatory clearance and December 31, 2020 per unit change in characteristics of the device’s predicates. Recalls are classified as Class I when there is potential for serious patient harm or death and Class II when there is potential for temporary or reversible patient harm or a slight chance of serious patient harm or death. Models adjust for

listed predicate and manufacturer characteristics, year fixed effects, and product type and manufacturer fixed effects when indicated. All standard errors are clustered at the manufacturer level.
f. “Non-matching predicate product types” refer to number of unique predicate product types that do not match product type of applicant device. Product types are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
g. “Non-matching predicate specialties” refer to number of unique predicate medical specialties that do not match specialty of applicant device.
h. “Ongoing” predicate recalls defined as Class I or Class II recalls classified by the FDA but not yet terminated at time of clearance for applicant device.

Sensitivity Analyses: Fixed Follow-up Period for Device Recalls

In our primary analyses, the outcome of interest was whether a device experienced at least one Class I or Class II recall between its FDA clearance and December 31, 2020, meaning follow-up for each device ranged from 2 to 17 years. We accounted for differences in follow-up periods by using year fixed effects, which adjusted for differences in recall probability across years, including decreases in recall probability in later years of our sample due to shorter follow-up periods.

As an alternative to our variable follow-up approach, we performed analyses in which our outcome of interest was whether a device experienced at least one Class I or Class II recall in the two years following its FDA clearance (i.e., a fixed follow-up period). The advantage of using a fixed follow-up period is that the outcome is homogeneously defined across devices, meaning estimated coefficients are more easily interpretable. However, using a fixed follow-up period also introduces a trade-off between statistical power and data availability. Using a relatively short follow-up period means more recently cleared devices can be included in the sample, but statistical power is decreased as recalls are rarer. In contrast, using a relatively long follow-up period results in greater statistical power as recalls are less rare, but only older devices can be included in the sample as recently cleared devices would not yet met the required follow-up period. We used a relatively short fixed follow-up period of two years in order to include all of the devices used in our primary analyses.

As expected, we observed fewer recalls when using a fixed follow-up period. 1,461 devices (4.2%) experienced at least one Class I/II recall within two years of their regulatory clearance (Table B2), in contrast to 4,007 devices (11.4%) that experienced at least one Class I/II recall between its regulatory clearance and December 31, 2020 (Table 1 in the main manuscript). Unadjusted comparisons between devices recalled and not recalled within a fixed follow-up period were comparable to comparisons between devices recalled and not recalled using a variable follow-up period. Devices that were recalled within two years of their regulatory clearance cited more predicates, newer predicates, predicates with more discordant product types and specialties, and more predicates with ongoing recalls compared to devices that were not recalled within two years of their regulatory clearance (Table B4).

Adjusted analyses using a fixed follow-up period differed slightly compared to adjusted analyses using a variable follow-up period. After adjusting for year, manufacturer, and product type fixed effects and manufacturer experience, increasing the mean age of predicates cited in a 510(k) submission by one year was significantly associated with a 0.09 percentage point (p.p.) decrease in the probability of experiencing a Class I/II recall in the two years following regulatory clearance (95% confidence interval [CI], -0.15 to -0.04) (Table B5). Increasing the age of the newest predicate cited was significantly associated with a 0.11 p.p. decrease in recall probability (95% CI, -0.19 to -0.02), while oldest predicate age was not significantly associated with recall probability.

Citing a predicate aged 10 years or older was not significantly associated with recall probability (Table B5). We found no significant associations between recall probability and predicate

dissimilarity, as measured by non-matching predicate product codes and non-matchong predicate medical specialties. In contrast to results using a variable follow-up period, citing additional predicates was not significantly associated with experiencing a Class I/II recall within two years of regulatory clearance. However, similar to results using a variable follow-up period, citing predicates with three or more on-going recalls was significantly associated with a 8.94 p.p. increase in in the probability of experiencing a Class I/II recall within two years of follow-up (95% CI, 3.51 to 14.37).

Overall, in comparison to models using a variable follow-up period, using a fixed follow-up period yielded similar results when examining the association between recall probability and predicate age and predicate recalls but smaller and statistically insignificant results when examining the association between recall probability and number of cited predicates.

eTable 7. Characteristics of 510(k) medical devices by recall status

	Recalled[a]		Not Recalled	
N	1,461		33,715	
Unique Manufacturers[b]	994		4,143	
Unique Product Types[c]	676		1,333	
Total Number Of Deaths In MAUDE Database	24,918		4,923	
	Mean	**Median**	**Mean**	**Median**
	(SD)	**(P25, P75)**	**(SD)**	**(P25, P75)**
Mean Age Of Predicates (Years)[d]	4.8	3.9	5.4	4.1
	(4)	(1.9, 6.7)	(4.6)	(2.1, 7.3)
Age Of Newest Predicate (Years)	2.8	1.6	3.7	2.1
	(3.3)	(0.8, 3.4)	(4.4)	(1, 4.6)
Age Of Oldest Predicate (Years)	7.3	5.7	7.4	5.7
	(6.3)	(2.4, 10.4)	(6.3)	(2.6, 10.5)
Number Of Predicates	3.0	2	2.6	2
	(3.2)	(1, 4)	(2.5)	(1, 3)
Number Of Unique Non-Matching Predicate Product Types	0.8	0	0.6	0
	(1.2)	(0, 1)	(1)	(0, 1)
Number Of Unique Non-Matching Predicate Medical Specialties[e]	0.2	0	0.2	0
	(0.5)	(0, 0)	(0.5)	(0, 0)
Number Of Prior 510(K) Clearances From Manufacturer	97.0	30	48.9	9
	(140.7)	(7, 125)	(98.8)	(2, 42)
Number Of Prior 510(K) Clearances From Manufacturer For Same Product Type	7.2	3	4.5	1
	(11.9)	(1, 9)	(9.3)	(0, 4)
	n (%)		**n (%)**	
At Least One Predicate Received FDA Clearance 10 Years Or More Prior To FDA Decision For Applicant Device	27.4%		27.0%	
Number of Ongoing Class I Or Class II Predicate Recall[f]				
0	1169 (80%)		31859 (94.5%)	
1	164 (11.2%)		1362 (4%)	
2	59 (4%)		299 (0.9%)	
≥ 3	69 (4.7%)		195 (0.6%)	
At Least One Ongoing Class I or Class II Predicate Recall by Reason[g]				
Miscellaneous	107 (7.3%)		662 (2%)	
Software	109 (7.5%)		396 (1.2%)	
Device Design Or Component	87 (6%)		409 (1.2%)	
Materials Or Composition	42 (2.9%)		258 (0.8%)	
Manufacturing Environment	40 (2.7%)		256 (0.8%)	
Labeling	28 (1.9%)		162 (0.5%)	
Packaging	11 (0.8%)		93 (0.3%)	
Application	1 (0.1%)		11 (0%)	

a. “Recalled” denotes whether a device experienced one or more Class I or Class II recall in two years after its regulatory clearance. Recalls are classified as Class I when there is potential for serious patient harm or death and Class II when there is potential for temporary or reversible patient harm or a slight chance of serious patient harm or death.

b. Variations on similar manufacturer names present in FDA databases are standardized into a single manufacturer name. See Appendix A for details.
c. “Product types” are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
d. Predicate age defined as number of years between clearance of predicate device and clearance of applicant device.
e. “Medical specialty” refers to 1 of the 19 FDA medical specialty review panels that are responsible for reviewing a medical device. Medial specialty review panels are assigned based on a medical device’s product type.
f. “Ongoing” predicate recalls defined as Class I or Class II recalls classified by the FDA but not yet terminated at time of clearance for applicant device.
g. Recalls were manually assigned to one of eight categories based on reason for recall (Appendix Table A3).

eTable 8. Change in probability of class I or II recalls of 510(k) medical devices by predicate characteristics

Adjustment for product type[a] and manufacturer fixed effects[b]	Unadjusted	Unadjusted	Unadjusted	Adjusted	Adjusted	Adjusted
Definition of predicate age[c]	Mean age	Oldest and newest age	10-year indicator	Mean age	Oldest and newest age	10-year indicator
N	35,176	35,176	35,176	35,176	35,176	35,176
Predicate Characteristics	**Percent Point Change in Probability of Class I or II Recall[d] per Unit Change in Predicate Characteristic (95% CI)**					
Mean Age of Predicates (Years)	-0.14 (-0.19, -0.08)	N/A	N/A	-0.09 (-0.15, -0.04)	N/A	N/A
Age of Newest Predicate (Years)	N/A	-0.14 (-0.21, -0.08)	N/A	N/A	-0.11 (-0.19, -0.02)	N/A
Age of Oldest Predicate (Years)	N/A	-0.02 (-0.08, 0.04)	N/A	N/A	0.00 (-0.07, 0.07)	N/A
One or More Predicate Aged 10 Years or Older	N/A	N/A	-0.70 (-1.33, -0.08)	N/A	N/A	-0.15 (-0.85, 0.55)
Number of Predicates	0.10 (-0.03, 0.23)	0.06 (-0.08, 0.20)	0.11 (-0.01, 0.24)	0.13 (-0.02, 0.28)	0.10 (-0.07, 0.26)	0.13 (-0.02, 0.28)
Number of Unique Non-matching Predicate Product Types[e]	0.02 (-0.52, 0.56)	0.00 (-0.54, 0.54)	0.04 (-0.51, 0.58)	-0.11 (-0.75, 0.52)	-0.13 (-0.77, 0.50)	-0.09 (-0.72, 0.55)
Number of Unique Non-matching Predicate Medical Specialties[f]	0.31 (-0.06, 0.67)	0.27 (-0.10, 0.64)	0.30 (-0.07, 0.67)	0.30 (-0.17, 0.78)	0.26 (-0.22, 0.74)	0.27 (-0.20, 0.75)
Number of Ongoing[e] Class I or Class II Predicate Recalls						
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	6.30 (4.55, 8.05)	6.28 (4.53, 8.03)	6.29 (4.54, 8.05)	1.59 (0.05, 3.13)	1.57 (0.03, 3.11)	1.56 (0.02, 3.10)
2	11.60 (7.59, 15.61)	11.56 (7.54, 15.57)	11.61 (7.60, 15.63)	3.25 (-0.23, 6.73)	3.22 (-0.27, 6.70)	3.24 (-0.24, 6.72)
≥3	20.90 (15.08, 26.71)	20.84 (15.01, 26.67)	20.91 (15.10, 26.72)	8.99 (3.59, 14.40)	8.94 (3.51, 14.37)	8.95 (3.54, 14.37)
Number of Prior 510(k) Clearances from Manufacturer	0.01 (0.01, 0.02)	0.01 (0.01, 0.02)	0.01 (0.01, 0.02)	0.01 (0.00, 0.02)	0.01 (0.00, 0.02)	0.01 (0.00, 0.02)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	0.02 (-0.03, 0.06)	0.02 (-0.03, 0.06)	0.02 (-0.03, 0.07)	-0.06 (-0.10, -0.03)	-0.06 (-0.10, -0.03)	-0.06 (-0.09, -0.03)

a. “Product types” are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
b. Variations on similar manufacturer names present in FDA databases are standardized into a single manufacturer name. See Appendix A for details.

c. Predicate age defined as number of years between clearance of predicate device and clearance of applicant device.
d. Linear probability models were used to model change in probability of applicant device experiencing a Class I or Class II recall within two years of its regulatory clearance per unit change in characteristics of the device's predicates. Recalls are classified as Class I when there is potential for serious patient harm or death and Class II when there is potential for temporary or reversible patient harm or a slight chance of serious patient harm or death. Models adjust for listed predicate and manufacturer characteristics, year fixed effects, and product type and manufacturer fixed effects when indicated. All standard errors are clustered at the manufacturer level.
e. "Non-matching product types" refer to number of unique predicate product types that do not match product type of applicant device. Product types are FDA-assigned identifiers describing the generic function of a medical device. See "Study Sample" subsection for details.
f. "Non-matching specialties" refer to number of unique predicate medical specialties that do not match specialty of applicant device. Medical specialty refers to 1 of the 19 FDA medical specialty review panels that are responsible for reviewing a medical device. Medial specialty review panels are assigned based on a medical device's product type.
g. "Ongoing" predicate recalls defined as Class I or Class II recalls classified by the FDA but not yet terminated at time of clearance for applicant device.

Sensitivity Analyses: Logistic Regression and Accelerated Failure Time Models

To supplement our results from linear probability models, we also estimated logistic regression and accelerated failure time models predicting Class I and Class II recalls as a function of predicate characteristics. Logistic regression models estimate the association between covariates and the log odds of binary event occurring (i.e., a Class I or Class II recall occurs). Accelerated failure time models are a type of survival model that estimate the association between covariates and the time until an event occurs (i.e., days until a Class I or Class II recall). Accelerated failure time models explicitly account for differences in exposure time (e.g., a device is more likely to experience a recall after having been on the market for one year compared to a device that has been on the market for one day), unlike our linear probability models, in which we indirectly accounted for exposure time by including year fixed effects. Accelerated failure time models are not dependent on the proportional hazards assumption, unlike the Cox proportional hazards model.[12]

Given concerns about biased fixed effects due to small group sizes, we only estimated logistic regression and accelerated failure time models with year, manufacturer, and medical specialty fixed effects, as opposed to year, manufacturer, and product type fixed effects. Medical device product types are hierarchically nested within medical specialties, meaning medical specialty fixed effects can be thought of as less granular than product type fixed effects.

Additionally, given that logistic regression models cannot estimate fixed effects for groups that never experience an outcome or always experience an outcome (e.g., a manufacturer that never has one of its devices recalled), the sample used to conduct the logistic regression analysis was necessarily smaller. As such, we estimated the accelerated failure time model and the linear probability model using the limited sample employed in the logistic regression analysis to ensure any potential differences between models were strictly due to differences in the estimation approach and not differences in sample composition. We also estimated linear probability models with the limited sample but with our preferred fixed effects specification (year, manufacturer, and product type), as well as with the full sample but with less granular fixed effects to understand whether any changes in effects were driven by changes in the sample vs changes in the fixed effects specification.

Overall, results were comparable across different modeling approaches (Table B6). All predicate characteristics maintained the same level of statistical significance and same sign across the linear probability model, logistic regression model, and accelerated failure time model. For example, after adjusting for year, manufacturer, and medical specialty fixed effects, increasing the age of a 510(k) medical device's newest predicate by one year was associated with a 0.386 percentage point decrease in recall probability (95% CI, -0.548 to -0.224) in the linear probability model, a 3.5% decrease in the odds of experiencing a recall (95% CI, 0.952 to 0.978), and a 3.5% increase in the time until experiencing a recall (95% CI, 1.022 to 1.047).

Among linear probability models, effect sizes generally increased as the sample size decreased and fixed effects become less granular (Table B6). Increases in the effect size for predicate age and number of predicates appeared to be attributable to both changes in the sample and use of

different fixed effects, while increases in the effect size for predicate recalls appeared largely attributable to the use of less granular fixed effects.

eTable 9. Change in adjusted probability of class I or II recalls of 510(k) medical devices by predicate characteristics as estimated by linear probability models, logistic regression

Model	LPM with Full Sample, Full FE[d]	LPM with Full Sample, No Product Type FE	LPM with Limited Sample, Full FE	LPM with Limited Sample, No Product Type FE	Logistic with Limited Sample, No Product Type FE[e]	AFT Model with Limited Sample, No Product Type FE[f]
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Manufacturer Fixed Effects[a]	Yes	Yes	Yes	Yes	Yes	Yes
Medical Specialty Fixed Effects[b]	No	Yes	No	Yes	Yes	Yes
Product Type Fixed Effects[c]	Yes	No	Yes	No	No	No
N	35,176	35,176	20,906	20,906	20,906	20,906
Predicate Characteristics	**Adjusted Change in Probability**	**Adjusted Change in Probability**	**Adjusted Change in Probability**	**Adjusted Change in Probability**	**Adjusted Odds Ratio**	**Adjusted Time Ratio**
Age of Newest Predicate (Years)[g]	-0.18 (-0.30, -0.07)	-0.25 (-0.37, -0.14)	-0.30 (-0.47, -0.13)	-0.38 (-0.54, -0.22)	0.96 (0.95, 0.98)	1.03 (1.02, 1.05)
Age of Oldest Predicate (Years)	0.04 (-0.06, 0.14)	0.05 (-0.05, 0.15)	0.08 (-0.06, 0.23)	0.08 (-0.06, 0.23)	1.01 (1.00, 1.02)	0.99 (0.98, 1.00)
Number of Predicates	0.48 (0.24, 0.72)	0.52 (0.28, 0.75)	0.63 (0.33, 0.93)	0.69 (0.41, 0.98)	1.04 (1.02, 1.06)	0.97 (0.95, 0.98)
Number of Unique Non-matching Predicate Product Types[h]	-0.24 (-1.21, 0.74)	-0.19 (-1.19, 0.81)	0.18 (-1.28, 1.64)	-0.15 (-1.63, 1.32)	0.99 (0.89, 1.10)	1.01 (0.92, 1.11)
Number of Unique Non-matching Predicate Medical Specialties[i]	-0.16 (-0.87, 0.55)	-0.29 (-0.97, 0.40)	-0.46 (-1.43, 0.51)	-0.46 (-1.39, 0.47)	0.97 (0.90, 1.03)	1.03 (0.97, 1.10)
Number of Ongoing Class I or Class II Predicate Recalls[j]						
0	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group	Reference Group
1	1.78 (-1.00, 4.56)	4.93 (2.22, 7.63)	2.03 (-1.34, 5.39)	6.01 (2.85, 9.16)	1.46 (1.23, 1.73)	0.70 (0.60, 0.81)
2	2.13 (-1.87, 6.13)	6.15 (1.90, 10.41)	2.44 (-2.05, 6.92)	6.83 (2.14, 11.52)	1.47 (1.15, 1.87)	0.68 (0.54, 0.85)
≥3	9.31 (2.84, 15.77)	14.85 (8.04, 21.67)	9.53 (2.53, 16.53)	15.87 (8.70, 23.03)	2.24 (1.63, 3.08)	0.48 (0.37, 0.62)
Number of Prior 510(k) Clearances from Manufacturer	-0.01 (-0.02, 0.00)	-0.01 (-0.02, 0.00)	0.00 (-0.01, 0.01)	0.00 (-0.01, 0.01)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
Number of Prior 510(k) Clearances from Manufacturer for Same Product Type	-0.08 (-0.14, -0.02)	-0.14 (-0.20, -0.08)	-0.08 (-0.15, -0.01)	-0.16 (-0.22, -0.09)	0.99 (0.98, 0.99)	1.01 (1.00, 1.02)

a. Variations on similar manufacturer names present in FDA databases are standardized into a single manufacturer name. See Appendix A for details.
b. “Medical specialty” refers to 1 of the 19 FDA medical specialty review panels that are responsible for reviewing a medical device. Medial specialty review panels are assigned based on a medical device’s product type.
c. “Product types” are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
d. Linear probability models were used to model change in probability of applicant device experiencing a Class I or Class II recall between its regulatory clearance and December 31, 2020 per unit change in characteristics of the device’s predicates. Recalls are classified as Class I when there is potential for serious patient harm or death and Class II when there is potential for temporary or reversible patient harm or a slight chance of serious patient harm or death. Models adjust for listed predicate and manufacturer characteristics, year fixed effects, and product type and manufacturer fixed effects when indicated. All standard errors are clustered at the manufacturer level.
e. Logistic regression models were used to estimate association between log odds of applicant device experiencing a Class I or Class II and the characteristics of the device’s predicates, with results reported as adjusted odds ratios.
f. Accelerated failure time models were used to estimate association between days between regulatory approval and experiencing a Class I or Class II and the characteristics of the device’s predicates (days at risk were censored at January 1st, 2021), with results reported as adjusted time ratios.
g. Predicate age defined as number of years between clearance of predicate device and clearance of applicant device.
h. “Non-matching product types” refer to number of unique predicate product types that do not match product type of applicant device. Product types are FDA-assigned identifiers describing the generic function of a medical device. See “Study Sample” subsection for details.
i. “Non-matching specialties” refer to number of unique predicate medical specialties that do not match specialty of applicant device. Medical specialty refers to 1 of the 19 FDA medical specialty review panels that are responsible for reviewing a medical device. Medial specialty review panels are assigned based on a medical device’s product type.
j. “Ongoing” predicate recalls defined as Class I or Class II recalls classified by the FDA but not yet terminated at time of clearance for applicant device.

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