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Project: Breakthrough innovation and learning by failure in the medical device industry

**Report on the development of medical devices filed to the Food and Drug Administration (FDA)**

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The project is based on data related to the medical devices filed by firms to the U.S. FDA, which has been collected thanks to the scraping procedure described in a specific deliverable (D1.3A) of the project. We collected data on medical devices filed to the FDA from 01/01/2000 to 31/12/2022. The present report synthesizes the main variables collected from the FDA website and is divided into four sections which are focused, respectively, on the authorization process, the medical devices, the applicant firms, and the product recalls.

**Section 1. The FDA authorization process of medical devices**

According to the FDA regulations, the choice of the right authorization pathway depends on the degree of risk associated with the focal medical device. The FDA classifies this risk into three Classes:

I. Medical devices that present minimal potential for harm. They are subject only to a comprehensive set of "general controls", which include establishment registration and device listing, that are applicable to all classes of devices;

II. Medical devices that present higher risk than Class I devices. For these devices general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but such assurance could be provided by implementing "special controls", which can include the promulgation of performance standards as well as post-market surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions);

III. Medical devices that sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. For these devices, general controls, by themselves, are insufficient and there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device.

Most Class I and some Class II medical devices do not require a premarket submission, while the other devices could be authorized following one of the four pathways depicted in Figure 1:

- 510(k) (PreMarket Notification - PMN): some class I and most class II devices, for which the applicant firm must demonstrate that the new device is "substantially equivalent" to a previously legally marketed device (predicate device) in terms of intended use, technological characteristics, and performance testing, as needed.
- De Novo Classification Request (DN - DEN): some class I and most class II devices, for which there is no legally marketed predicate device. In these cases, the applicant firm must provide reasonable assurance of safety and effectiveness for the intended use by using general controls alone, or general and special controls.
- PMA (PreMarket Approval): class III devices, for which the applicant firm must provide valid scientific evidence demonstrating reasonable assurances of safety and effectiveness for the device's intended use.
- HDE (Humanitarian Device Exemption): class III devices that are intended to benefit patients with rare diseases or conditions (lower than 4,000 patients in the U.S.).

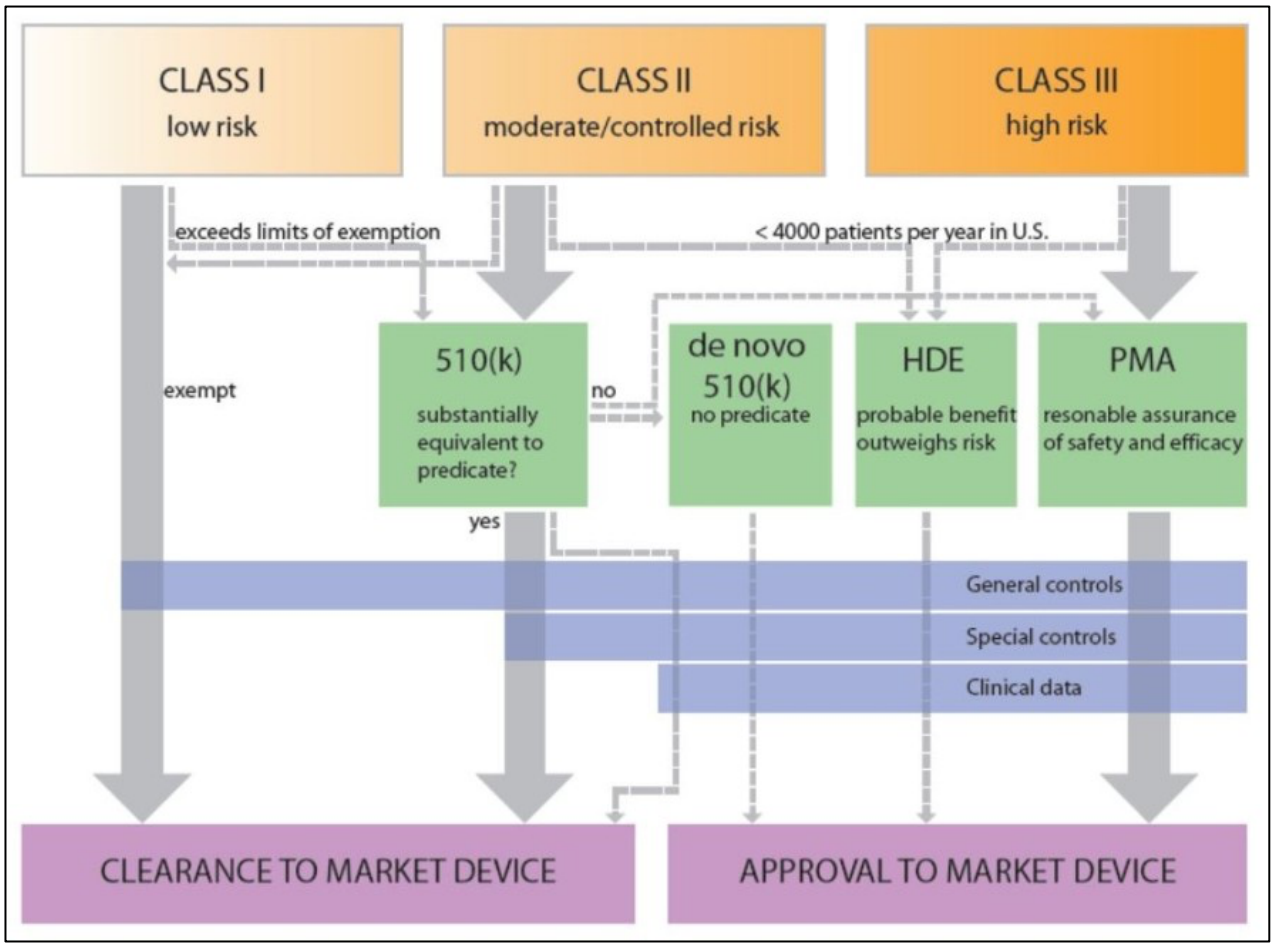


Figure 1. FDA pathways for the authorization of medical devices

In our research project, we collected the data of the medical devices filed in accordance with the first three pathways, while we neglected HDE devices, because of the limited data made available by the FDA on these devices.

As shown in Figure 2, the most used pathway is 510(k), which has been adopted for 72,627 medical devices, which represents more than 64 percent of the medical devices filed to the FDA. The second most used pathway is PMA, with 40,156 submissions. These submissions could be divided into "original PMA", which represents a totally new medical device, and "supplement PMA", which represents a change affecting the safety or effectiveness of a device for which the applicant has an approved PMA. In our data, we collected 745 original PMA, 77 of which without any supplement in the period under analysis, and 39,411 supplement PMA, of which 16,062 are supplements of PMA devices submitted before 2000. Finally, in our data we have 373 De Novo submissions.

As shown in Figure 2, the number of 510(k) submissions remains stable over the years, while PMA submissions passed from about 500 in 2000 to more than 2,500 in 2018, while in the last years they decreased to about 2000. Conversely, the number of De Novo submission is less regular, due to the limited use of this pathway by applicant firms.

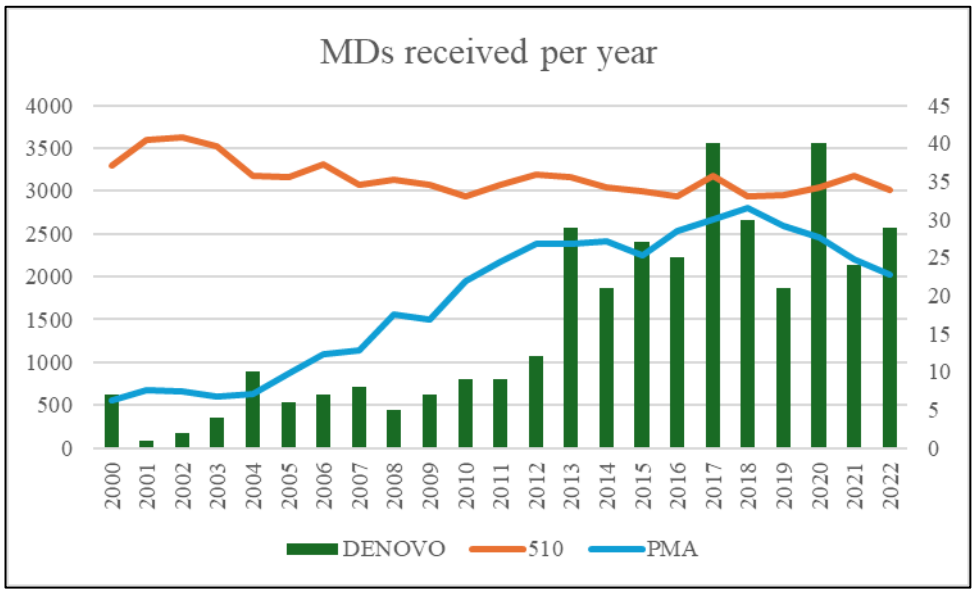


Figure 2. Number of medical devices filed under the three FDA pathways

The three pathways discussed above could be further detailed by considering the submission programs used for the filing of the medical devices.

In particular, medical devices that choose the 510(k) pathway could select the following three programs:

- Traditional, which may be used for any original 510(k) or for a change to a previously cleared

device under 510(k).

- Special, which may be used for changes to their own existing device if the method(s) to evaluate the change(s) are well-established, and when the results can be sufficiently reviewed in a summary or risk analysis format.
- Abbreviated, which may be used when the submission relies on FDA guidance document(s), demonstration of compliance with special control(s) for the device type, or voluntary consensus standard(s).

When a certain medical device adopts more than one submission program, it is labelled as a "dual track". As shown in Table 1, most of 501(k) adopt a traditional submission program, while about 19 percent of them choose the special one, and only 4 percent the abbreviated one.

In the case of De Novo devices, most of them adopt an abbreviated submission program, while less than 28 percent choose the dual track.

Concerning the PMA devices, original PMA devices are filed through the "Normal 180 Day Track", while there is a wider variety of submission programs for supplement PMAs:

- The "Normal 180 Day Track" program could be used for medical devices that, compared with the original, contain changes that affect the product safety and effectiveness or imply modifications in components, materials, design, specification, software, colour additives, or labelling. In these cases, the clinical data provided in support of the approval of the original PMA should still be applicable in supporting the approval of the changed device. In most cases, only new preclinical testing is needed to support safety and effectiveness. An in-depth review and approval by FDA are required before implementation of the change, while a full PMA review may be required. The criteria for a full PMA review include changes in the device that may raise different types of safety and effectiveness questions or changes in which there may be no accepted test methods for evaluating the issues of safety or effectiveness.
- The "Normal 180 Day Track No User Fee" program is similar to the previous one, but no user fee is required. The exemption from user fee can be granted when the supplement device differs from the original in term of the location of a manufacturer, sterilizer, packager, or supplier, when the FDA requires a Post-Approval Study (PAS), when there is a label change that is purely administrative or required by the FDA, or in the case of paediatric-only devices.
- The "30-Day Notice" program could be used for modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of the device. When the change qualifies as a 30day Notice, the change may be made 30 days after FDA receives the 30-day notice

unless FDA informs the PMA holder that the 30-day Notice is not adequate and describes the additional information or action required.

- The "135 Review Track For 30-Day Notice" program is similar to the previous one and is used when the 30-day Notice was not adequate, but contained data meeting appropriate content requirements for a PMA supplement.
- The "Special (Immediate Track)" program could be used for changes, including certain labelling and manufacturing ones, that enhance the safety of the device or the safety in the use of the device. This program may be placed into effect by the applicant prior to the receipt of a written FDA order approving the PMA supplement.
- The "Panel Track" program could be used for changes that request a significant change in design or performance of the device, or a new indication for use of the device. In these cases, substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness, as well as a full PMA review, which may include a review by an outside advisory panel.
- The "Real-Time Process" program could be used for a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labelling, and for which the applicant has requested, and the FDA has granted a meeting or similar forum to jointly review and determine the status of the supplement.

As shown in Table 1, the most frequent program for PMA supplements is the "30-Day Notice", followed by "Real-Time Process", which are related to minor changes from the original PMA.

| | **510(k)** | **DE NOVO** | **PMA** |
|---|---|---|---|
| **Traditional** | 56,431 | 0 | 0 |
| **Special** | 13,812 | 0 | 0 |
| **Abbreviated** | 2,352 | 269 | 0 |
| **Dual Track** | 32 | 104 | 0 |
| **Normal 180 Day Track** | 0 | 0 | 4,667 |
| **Normal 180 Day Track No User Fee** | 0 | 0 | 2,803 |
| **30-Day Notice** | 0 | 0 | 22,542 |
| **135 Review Track For 30-Day Notice** | 0 | 0 | 2,401 |
| **Special (Immediate Track)** | 0 | 0 | 1,490 |
| **Panel Track** | 0 | 0 | 310 |
| **Real-Time Process** | 0 | 0 | 5,935 |
| **Missing data** | 0 | 0 | 8 |

Table 1. Number of medical devices filed under the different submission programs

Some medical devices can be submitted, rather than directly to the FDA, to some accredited Third Parties,

such as Global Quality and Regulatory Services, LLC and Regulatory Technology Services, LLC. This approach should yield a streamlined review process.

As shown in Table 2, only 4 percent of 510(k) devices and 4 permille of PMA ones involve an accredited Third Party in the filing procedure.

| Third party procedure? | No | Yes |
|---|---|---|
| **510(k)** | 69,436 | 3,191 |
| **DENOVO** | 373 | 0 |
| **PMA** | 39,976 | 180 |

Table 2. Number of medical devices filed under the third party procedure

As mentioned above, 510(k) submissions are based on the identification of at least one "predicate device", which is a previously legally marketed device which is substantially equivalent to the focal device, in terms of intended use, technological characteristics, and performance testing. Other than predicates, sometimes 510(k) submissions also identify some "reference devices", which may be used to support scientific methodology or standard reference values that are necessary to evaluate the effects on safety and effectiveness of the new or different characteristics of the focal device.

We retrieved the predicate and reference devices of the 510(k) medical devices filed to the FDA through a structured approach based on the following steps:

1. A Python search program applied to all the "Summary" .pdf files submitted by the applicant firm to the FDA. We also applied the same Python search program to all the "Statement" .pdf files, which typically contain less information than "Summary", but could be filed in combination or in substitution with the "Summary" by the applicant firm.
2. A Foxit search function applied to all the "Summary" .pdf files submitted by the applicant firm to the FDA, combined with some VBA macros based on the analysis of the position of keywords, such as "predicate device", "primary predicate", and "reference device". We also applied the same Foxit search program and VBA macros to all the "Statement" .pdf files, which typically contain less information than "Summary", but could be filed in combination or in substitution with the "Summary" by the applicant firm.
3. A comparison of the data collected in the first two steps with the predicate and reference devices indicated in https://dev-510k.innolitics.com/. This website presents the scanned version of the "Summary" and "Statement" files, which have been analyzed through some AI tool to identify the predicate and reference devices. Nevertheless, this website is affected by several false negatives (e.g. missing data due to the lack of the KNumber of predicate and reference devices) and false

positive (e.g. incorrect data due to the presence of KNumbers that are associated with neither predicate nor reference devices, but with devices that are component or complementary with the focal medical device).

4. Manual check of all the "Summary" or "Statement" .pdf files characterized by contrasting results obtained with the three previous methods.

Thanks to these steps, we identified 139,563 predicate and reference devices associated with the 510(k) in our sample. We manually checked 35,190 "Summary" or "Statement" files, while 5,810 files are not available, and 32,000 files were not manually checked. Compared with Innolitics, we found 18,726 predicate and reference devices that are included in our list and have been not indicated by Innolitics (13.4% of total number), while 8,623 predicates indicated by Innolitics are wrong (6.2% of total number of predicates).

The distribution of the number of predicate and reference devices for each 510(k) device is presented in Table 3. More than 11,000 510(k) devices do not indicate any predicate or reference device, even if this number is inflated by the 5,810 devices for which neither the "Summary" nor "Statement" files are available. Almost 40 percent of the 510(k) devices indicate only one predicate, while more than 600 510(k) devices present more than 10 predicate or reference devices. The device "SMITH & NEPHEW, INC. HIP SYSTEM INSTRUMENTATION" presents the maximum number (101) of predicate and reference devices.

| Number of predicate and reference devices | Number of 510(k) |
|---|---|
| 0 | 11,079 |
| 1 | 29,013 |
| 2 | 15,245 |
| 3 | 7,638 |
| 4 | 4,042 |
| 5 | 2,073 |
| 6 | 1,254 |
| 7 | 708 |
| 8 | 463 |
| 9 | 305 |
| 10 | 205 |
| From 11 to 20 | 516 |
| From 21 to 30 | 58 |
| From 31 to 40 | 18 |
| From 41 to 50 | 4 |
| From 51 to 100 | 5 |
| 101 | 1 |

Table 3. Number of medical devices by number of predicate and reference devices

The time necessary for the approval of the medical devices strongly depends on the pathway chosen by the applicant firm. In particular, the average time from the date of the application of the medical device and the date of the FDA decision on the same device is 115.74 days. As shown in Table 4, the PMA pathway seems faster than the other ones. Nevertheless, this result is due only to the supplement PMA devices, whose average approval time is 77.32 days. Conversely, original PMA devices, whose authorization process is more complex, require more than 480 days, on average. Even the comparison between the speed of De Novo versus 510(k) shows that the former is quite slower than the latter, because the lack of predicates increases the time needed to evaluate the safety and effectiveness of a De Novo medical device.

| | Mean | Coeff. Var. | <1 year | <2 years | <3 years | <4 years | <5 years | >5 years |
|---|---|---|---|---|---|---|---|---|
| **510(k)** | 131.73 | 0.85 | 95.70% | 4.13% | 0.15% | 0.01% | 0.00% | 0.00% |
| **DE NOVO** | 341.74 | 0.97 | 65.15% | 29.76% | 2.68% | 1.61% | 0.27% | 0.54% |
| **PMA** | 84.81 | 1.74 | 96.31% | 2.84% | 0.50% | 0.24% | 0.04% | 0.06% |
| **PMA original** | 480.84 | 0.87 | 52.21% | 31.81% | 8.99% | 4.56% | 0.67% | 1.74% |
| **PMA supplement** | 77.32 | 1.63 | 97.15% | 2.30% | 0.34% | 0.16% | 0.03% | 0.03% |

Table 4. Time to approval by FDA pathway

As shown in Table 5, the approval process of a 510(k) medical device typically ends with the definition of its substantially equivalence with one or more predicate devices, previously approved by the FDA. Nevertheless, the approval process may also result in different decisions when the substantially equivalence is accompanied by some limitations and indications to ensure its safety:

- "Substantially Equivalent - With Limitations": The device is cleared but restricted in its use, often regarding specific anatomical sites, populations, or environments.
- "Substantially Equivalent for Some Indications": The new device is only approved for a subset of the indications listed for the predicate, not for the entire range of uses.
- "Substantially Equivalent with Drug": The device component is cleared, but any drug components within it are not covered by the 510(k) approval and must meet CDER drug requirements.
- "Substantially Equivalent – Kit": Applies to a package containing multiple devices. The overall kit is cleared, but individual components may have restrictions.
- "Substantially Equivalent - Kit with Drugs": A kit containing both medical devices and drugs. Similar to "Substantially Equivalent with Drug", the device parts are cleared while the drug components are subject to separate regulations.
- "Substantially Equivalent - Subject to Tracking Regulation": A device that is substantially

equivalent but must be tracked through the distribution chain from the manufacturer to the user to manage risks.

As shown in Table 5, only "Substantially Equivalent - With Limitations" and "Substantially Equivalent – Kit" appear more than one hundred times in the observed period.

While all the De Novo medical devices have been granted as such, the final decision for the medical devices filed under the PMA pathway is usually "30 day notice acceptance", for the supplement PMA under the "30-Day Notice" program, or the "Approval". Original PMA medical devices, when they are not approved, could result in a "Withdrawal after approval" or, more rarely, in a "Reclassification after approval", when the PMA device has been reclassified to a different risk class (e.g., from Class III to Class II) after its initial approval, or in a "Conversion after approval", when a medical device is converted into a PMA once it has been already approved.

| | 510(k) | DENOVO | PMA |
|---|---|---|---|
| **Substantially Equivalent** | 71,990 | 0 | 0 |
| **Substantially Equivalent - With Limitations** | 385 | 0 | 0 |
| **Substantially Equivalent for Some Indications** | 15 | 0 | 0 |
| **Substantially Equivalent with Drug** | 5 | 0 | 0 |
| **Substantially Equivalent - Kit** | 189 | 0 | 0 |
| **Substantially Equivalent - Kit with Drugs** | 16 | 0 | 0 |
| **Substantially Equivalent - Subject to Tracking Regulation** | 27 | 0 | 0 |
| **Granted De Novo** | 0 | 373 | 0 |
| **Approval** | 0 | 0 | 17,448 |
| **30 day notice acceptance** | 0 | 0 | 22,543 |
| **Reclassification after approval** | 0 | 0 | 45 |
| **Conversion after approval** | 0 | 0 | 3 |
| **Withdrawal after approval** | 0 | 0 | 117 |

Table 5. Type of final decision by FDA pathway

**Section 2. The features of medical devices filed to the FDA**

As discussed in the previous section, the most important features of medical devices, which also affects the pathway used for their authorization, is its risk class. As shown in Table 6, most PMA medical devices are classified as Class III, while a small minority is Class II. The presence of Class II devices approved under the PMA pathway could be due to the reclassification of the risk related to these devices, because the maturation of the related technology leads to have a more predictable safety profile. Likewise, most 510(k) medical devices are classified as Class II, while a small minority is Class III. The presence of Class III devices approved under the 510(k) pathway is because, before the approval of Medical Device Amendments in 1976 that states that Class III devices must be checked using the tight PMA pathway, some Class III devices had been already authorized using the less stringent 510(k) pathway. These Class III devices, called "Pre-Amendment" Class III devices, could be used as predicates by new Class III devices, which could be still authorized using the 510(k) pathway, until the FDA will regulate the approval of these devices under the PMA pathway.

| | I | II | III | Unclassified |
|---|---|---|---|---|
| **510(k)** | 5,002 | 65,752 | 308 | 1,565 |
| **DE NOVO** | 8 | 365 | 0 | 0 |
| **PMA** | 0 | 1,216 | 38,801 | 139 |

Table 6. Number of MDs by risk class and FDA pathway

The FDA also evaluates the implantable nature of the medical devices, which are intended to be placed in a surgically or naturally formed cavity of the human body for at least one month. The distribution of implanted devices by FDA pathways is presented in Table 7, which shows that the highest prevalence of implanted devices occurred in the PMA pathway, since more than thirty percent of PMA medical devices are implanted.

| Implanted device? | No | Yes |
|---|---|---|
| **510(k)** | 70,258 | 2,369 |
| **DE NOVO** | 363 | 10 |
| **PMA** | 27,835 | 12,321 |

Table 7. Number of medical devices by implanted nature and FDA pathway

Another variable that is tracked by the FDA is the life-sustaining nature of the medical devices, which could be assigned to devices that are essential to the restoration or continuation of a bodily function that is important to the continuation of human life. As shown in Table 8, even in this case the highest prevalence of life-sustain/support devices occurred in the PMA pathway, since more than sixty percent of PMA medical devices are implanted. In any case, even about 23 percent of 510(k) devices are life-sustain/support devices.

| Life-sustain/support device? | No | Yes |
|---|---|---|
| **510(k)** | 56,068 | 16,559 |
| **DE NOVO** | 344 | 29 |
| **PMA** | 15,592 | 24,564 |

Table 8. Number of medical devices by life-sustain/support nature and FDA pathway

Some medical devices are based on the combination of different products, such as drugs, devices, and biological products, which should be authorized by using several approval processes. The FDA identifies these combined medical devices, which represent a small minority in the whole population of the devices filed by the FDA, as shown in Table 9.

| Combined device? | No | Yes |
|---|---|---|
| **510(k)** | 71,702 | 925 |
| **DE NOVO** | 373 | 0 |
| **PMA** | 40,152 | 4 |

Table 9. Number of medical devices by combined nature and FDA pathway

Each medical device is associated by the FDA with at least one specific technological class, called Product Class (PC). In the presence of more PCs associated with a device, the FDA identifies a main PC and the other subsequent PCs. The existing PCs are almost 7,000 in total, but the medical devices filed between 2000 and 2022 are associated with only 3,027 different PCs. The distribution of medical devices into these PC classes in highly skewed, as indicated by the value of the Herfindahl Hirschman Index equal to 41.66.

The most numerous PC class includes 2,276 medical devices filed to the FDA in the period under analysis. These PCs are clustered into 20 regulations, which are associated with specific medical specialties. This classification of PCs allows a more effective evaluation of MDs, for panels of experts, specifically associated with a given regulation, are responsible. Indeed, each regulation characterizes the design, clinical evaluation, manufacturing, packaging, labelling, and post-market surveillance of the related MDs. As shown in Table 10, the highest number of devices is filed in the "Cardiovascular" regulation, especially for PMA devices, followed by "Orthopedic" and "General and Plastic Surgery". On the other hand, only 16 medical devices have been filed into the "Molecular Genetics" regulation. The same table also shows the number of associated PCs.

| | 510(k) | | DE NOVO | | PMA | |
|---|---|---|---|---|---|---|
| | **MDs** | **Main PCs** | **MDs** | **Main PCs** | **MDs** | **Main PCs** |
| **Anesthesiology** | 2,709 | 105 | 10 | 10 | 202 | 10 |
| **Cardiovascular** | 8,956 | 214 | 27 | 26 | 22,152 | 89 |
| **Clinical Chemistry** | 3,180 | 200 | 25 | 25 | 1,047 | 9 |
| **Dental** | 6,109 | 149 | 5 | 5 | 244 | 9 |
| **Ear, Nose, & Throat** | 821 | 61 | 14 | 14 | 716 | 8 |
| **Gastroenterology & Urology** | 4,274 | 244 | 36 | 36 | 1,932 | 28 |
| **General & Plastic Surgery** | 8,060 | 245 | 35 | 35 | 2,042 | 19 |
| **General Hospital** | 6,192 | 162 | 16 | 16 | 610 | 4 |
| **Hematology** | 960 | 91 | 6 | 6 | 0 | 0 |
| **Immunology** | 1,053 | 139 | 26 | 26 | 692 | 12 |
| **Microbiology** | 1,691 | 191 | 53 | 52 | 2,352 | 18 |
| **Molecular Genetics** | 10 | 4 | 6 | 6 | 0 | 0 |
| **Neurology** | 3,181 | 126 | 38 | 37 | 2,261 | 18 |
| **Obstetrics/Gynecology** | 1,827 | 110 | 15 | 15 | 532 | 14 |
| **Ophthalmic** | 1,482 | 105 | 15 | 15 | 2,502 | 25 |
| **Orthopedic** | 11,186 | 153 | 12 | 12 | 1,771 | 29 |
| **Pathology** | 19 | 8 | 7 | 7 | 859 | 20 |
| **Physical Medicine** | 1,937 | 81 | 5 | 5 | 10 | 3 |
| **Radiology** | 8,018 | 96 | 13 | 13 | 214 | 11 |
| **Toxicology** | 960 | 91 | 11 | 11 | 18 | 5 |
| **Total** | 72,627 | 2,570 | 373 | 370 | 40,156 | 331 |

Table 10. Number of medical devices and main PC class by FDA pathway and Regulation

In general, the number of PCs tends to be correlated with the number of medical devices associated with

the same regulation, but some regulations, such as "Microbiology" are characterized by a large number of PCs, while a not so large number of medical devices. Concerning De Novo, the number of medical devices is usually equal to the number of PCs, except for the few cases when two medical devices, associated with the same PC, are authorized in the same day.

Regarding the medical devices associated with more than one PC, Table 11 shows that there are a minority, compared to the devices associated with only one PC that represent almost 84 percent of the total number of medical devices authorized by the FDA. The medical device associated with the highest number of PCs is the "COBAS 8000 MODULAR SERIES ANALYZER", which is associated with 78 PCs, but most of the medical devices are characterized by a lower number of PCs.

| Number of associated PCs | Number of 510(k) | Number of DE NOVO | Number of PMA |
|---|---|---|---|
| **1** | 55,968 | 373 | 38,586 |
| **2** | 10,109 | 0 | 1,384 |
| **3** | 4,013 | 0 | 129 |
| **4** | 1,150 | 0 | 56 |
| **5** | 566 | 0 | 1 |
| **>5** | 823 | 0 | 0 |

Table 11. Number of medical devices by number of PC classes and FDA pathway

**Section 3. The features of applicant firms that filed medical devices to the FDA**

The FDA does not use a univocal name for each applicant firm. For this reason, we had to perform a standardization process, supported by the ORBIS database, to univocally identify the firms involved in the submission of medical devices to the FDA.

To reduce the impact of legal and organizational issues, we codified each applicant firm at the corporate group level. This implies the identification of the corporate group to which each applicant firm belonged at the filing date of each medical device. Considering the large number of mergers and acquisitions in the medical device industry, we had to identify them by combining information from the ORBIS database to other data collected from the Zephyr database and other open sources. Once identified the corporate group of each applicant firm, we associated each medical device with the holding of this corporate group.

After this procedure, we could identify 13,502 different independent applicant firms, which come from 79 countries. As shown in Table 12, most of these firms filed 510(k) devices, while the application of PMA devices has been carried out only by fewer firms, even because of its larger costs.

| | 510(k) | DE NOVO | PMA | Total MDs |
|---|---|---|---|---|
| **Applicants** | 13,273 | 309 | 368 | 13,502 |
| **Countries** | 79 | 20 | 71 | 79 |

Table 12. Number of applicant firms and their country of origin by FDA pathway

In total, 75 percent of applicant firms developed three or fewer MDs. The 25 applicant firms that developed the highest number of medical devices filed to the FDA are presented in Table 13. The most productive firm is Medtronic, which filed more than 25 percent of PMA devices and almost 1,200 510(k) devices. The eight most productive firms filed more than one thousand medical devices to the FDA. The firms with the highest number of De Novo submissions is Artuma Holding, which controls the Roche group.

| | 510(k) | DE NOVO | PMA | Total MDs |
|---|---|---|---|---|
| **Medtronic** | 1,197 | 4 | 10,511 | 11,712 |
| **Boston Scientific** | 542 | 1 | 5,537 | 6,080 |
| **Abbott** | 389 | 3 | 4,391 | 4,783 |
| **Johnson & Johnson** | 1,142 | 2 | 1,863 | 3,007 |
| **Artuma Holding gmbh** | 492 | 8 | 1,213 | 1,713 |
| **Siemens ag** | 950 | 2 | 445 | 1,397 |
| **Stryker** | 973 | 3 | 120 | 1,096 |
| **Edwards Lifesciences** | 136 | 2 | 928 | 1,066 |
| **GE Healthcare** | 904 | 1 | 63 | 968 |
| **W.L. Gore & Associates, inc.** | 62 | 0 | 822 | 884 |
| **Biotronik se & co. kg** | 63 | 0 | 810 | 873 |
| **Koninklijke Philips n.v.** | 711 | 2 | 100 | 813 |
| **Biomet** | 574 | 0 | 201 | 775 |
| **Alcon ag** | 76 | 0 | 692 | 768 |
| **Zimmer Biomet** | 564 | 1 | 161 | 726 |
| **Becton, Dickinson & Co.** | 470 | 1 | 209 | 680 |
| **Integra Lifesciences** | 267 | 0 | 390 | 657 |
| **Cook Medical** | 492 | 3 | 153 | 648 |
| **Smith & Nephew plc** | 508 | 0 | 128 | 636 |
| **CR Bard** | 320 | 0 | 232 | 552 |
| **Hologic** | 119 | 1 | 389 | 509 |
| **St. Jude Medical** | 177 | 0 | 319 | 496 |
| **Synthes** | 355 | 0 | 107 | 462 |
| **The Cooper Companies, inc.** | 73 | 0 | 378 | 451 |
| **Microport Scientific Corporation** | 42 | 0 | 396 | 438 |

Table 13. Number of medical devices by FDA pathway filed by the top 25 applicant firms

Despite the majority of the most productive firms are from the U.S., a large number of medical devices are headquartered in other countries. Table 14 presents the number of medical devices filed by firms located in different regions, which were defined considering their geographical closeness and institutional proximity. This table shows the relevant role played by firms located in the European Union, even because of the presence of some large multinationals whose headquarters are in Ireland. The third most productive region is China, followed by East Asian countries, which also include Japan and South Korea. The other Anglo-Saxon countries, such as United Kingdom, Canada, and Australia, developed in total more than 5,200 medical devices, while the large number of medical devices filed by applicant firms from Other European countries is mainly due to Swiss firms. Finally, it is interesting to note the high number of

medical devices filed by Israeli firms, which are mostly focused on very innovative technologies, differently from firms located in Southeast Asian countries, which mainly filed traditional "simple" devices, as those based on latex. The other geographical areas have a very limited role in the development of medical devices filed to the FDA.

| | 510(k) | DE NOVO | PMA | Total MDs |
|---|---|---|---|---|
| **African countries** | 80 | 0 | 0 | 80 |
| **Anglo-Saxon countries** | 3,840 | 24 | 1,422 | 5,286 |
| **China** | 6,136 | 0 | 0 | 6,136 |
| **East Asian countries** | 5,169 | 2 | 787 | 5,958 |
| **European Union** | 10,901 | 43 | 3,134 | 14,078 |
| **Indian countries** | 254 | 0 | 0 | 254 |
| **Israel** | 1,475 | 17 | 142 | 1,634 |
| **Latin American countries** | 222 | 1 | 0 | 223 |
| **Middle East countries** | 82 | 0 | 0 | 82 |
| **Other European countries** | 2,464 | 13 | 2,375 | 4,852 |
| **Southeast Asian countries** | 1,083 | 1 | 3 | 1,087 |
| **United States of America** | 40,921 | 272 | 32,293 | 73,486 |

Table 14. Number of medical devices by FDA pathway and geographical region

Table 15 presents more detailed data, showing the number of medical devices developed by firms located in different countries, with a focus on the 25 most productive countries. Apart from the United States, the most productive countries are EU ones, such as Germany, Italy, France, Netherlands, Sweden, Denmark, Ireland, Spain, Belgium, Austria, and Finland. A relevant role is also played by Asian countries, such as Japan, South Korea, Taiwan, Malaysia, India, Singapore, other than China. It is interesting to note the role of Cayman Islands, which is due to the presence of firms located in this country, especially for fiscal and legal reasons.

| | 510(k) | DE NOVO | PMA | Total MDs |
|---|---|---|---|---|
| **United States** | 40,921 | 272 | 32,293 | 73,486 |
| **Germany** | 4,471 | 7 | 1,668 | 6,146 |
| **Switzerland** | 2,246 | 13 | 2,374 | 4,633 |
| **China** | 4,405 | 0 | 0 | 4,405 |
| **Japan** | 3,081 | 2 | 787 | 3,870 |
| **United Kingdom** | 2,131 | 13 | 511 | 2,655 |
| **South Korea** | 2,088 | 0 | 0 | 2,088 |
| **Taiwan** | 1,731 | 0 | 0 | 1,731 |
| **Israel** | 1,475 | 17 | 142 | 1,634 |
| **Italy** | 1,218 | 2 | 319 | 1,539 |
| **France** | 1,375 | 6 | 106 | 1,487 |
| **Netherlands** | 1,000 | 6 | 271 | 1,277 |
| **Canada** | 1,015 | 9 | 170 | 1,194 |
| **Sweden** | 798 | 7 | 237 | 1,042 |
| **Australia** | 392 | 2 | 344 | 738 |
| **Malaysia** | 662 | 1 | 0 | 663 |
| **Denmark** | 432 | 2 | 147 | 581 |
| **Ireland** | 424 | 6 | 98 | 528 |
| **Cayman Islands** | 77 | 0 | 396 | 473 |
| **Spain** | 340 | 2 | 0 | 342 |
| **Belgium** | 324 | 3 | 0 | 327 |
| **Austria** | 152 | 1 | 140 | 293 |
| **India** | 239 | 0 | 0 | 239 |
| **Finland** | 218 | 1 | 0 | 219 |
| **Singapore** | 166 | 0 | 3 | 169 |

Table 15. Number of medical devices by FDA pathway filed by applicant firms from the top 25 countries

Although almost 65 percent of medical devices filed to the FDA are developed by U.S. firms, this percentage varies a lot in different Regulations. In particular, in the "Ear, Nose, & Throat" regulation, less than 40 percent of the medical devices are filed by U.S. firms, as shown in Table 16. Even "Radiology", "Immunology", "Dental", and "General Hospital" regulations are characterized by a prevalence of foreign firms.

To better understand the role played by foreign firms, we counted the number of PCs within each Regulation where there are no devices filed by U.S. firms. In total, as shown in Table 17, 402 PCs were covered only by devices filed by foreign firms, with more than 30 PCs in regulations, such as "Gastroenterology & Urology", "Immunology", "Cardiovascular", and "Microbiology". On the other

hand, only "Molecular Genetics" and "Pathology" are characterized by less than 10 PCs without any medical device developed by U.S. firms.

| Regulation | Share on total number of MDs |
|---|---|
| **Anesthesiology** | 57.72% |
| **Cardiovascular** | 83.25% |
| **Clinical Chemistry** | 61.95% |
| **Dental** | 47.40% |
| **Ear, Nose, & Throat** | 37.78% |
| **Gastroenterology & Urology** | 65.99% |
| **General & Plastic Surgery** | 60.59% |
| **General Hospital** | 49.88% |
| **Hematology** | 52.80% |
| **Immunology** | 46.30% |
| **Microbiology** | 50.54% |
| **Molecular Genetics** | 75.00% |
| **Neurology** | 71.62% |
| **Obstetrics/Gynecology** | 60.11% |
| **Ophthalmic** | 53.29% |
| **Orthopedic** | 72.70% |
| **Pathology** | 56.38% |
| **Physical Medicine** | 51.79% |
| **Radiology** | 42.52% |
| **Toxicology** | 65.22% |
| **Total** | 64.94% |

Table 16. Share of medical devices filed by US applicant firms in each regulation

Thanks to the FDA website, it is also possible to evaluate the role played by the applicant firm. Indeed, this firm is not necessarily the developer of the focal medical device, but could act one of the following roles:

- Manufacturer, which is a firm that produces a medical device, by making chemical, physical, biological, or other procedures. A manufacturer could be also a simple "Kit Assembler", which places a finished device developed by another firm into a kit, without modifying the device or changing its intended use, or a "Manufacturer of Accessories or Components Ready for Use", which packages or labels the product ready to be used for "health related purposes" to end user;

| Regulation | Main PCs |
|---|---|
| **Anesthesiology** | 17 |
| **Cardiovascular** | 31 |
| **Clinical Chemistry** | 28 |
| **Dental** | 27 |
| **Ear, Nose, & Throat** | 13 |
| **Gastroenterology & Urology** | 35 |
| **General & Plastic Surgery** | 29 |
| **General Hospital** | 12 |
| **Hematology** | 15 |
| **Immunology** | 34 |
| **Microbiology** | 31 |
| **Molecular Genetics** | 2 |
| **Neurology** | 13 |
| **Obstetrics/Gynecology** | 20 |
| **Ophthalmic** | 25 |
| **Orthopedic** | 19 |
| **Pathology** | 9 |
| **Physical Medicine** | 12 |
| **Radiology** | 15 |
| **Toxicology** | 15 |
| **Total** | 402 |

Table 17. Number of main PCs without any medical device filed by US applicant firms in each regulation

- Remanufacturer, which is a firm that processes, conditions, renovates, repackages, restores, or does any other act to a finished device, making significant changes to its performance, safety specifications, or intended use;
- Specification Developer, which is a firm that develops specifications for device distributed under its own name, without performing any manufacturing and using a contract manufacturer to make finished device;
- Contract Manufacturer, which is a firm that arranges manufacturing a device for or on behalf of another firm, usually a specification developer or any other person;
- Contract Sterilizer, which is a firm that sterilizes a device for or on behalf of another firm, usually a specification developer or any other person;
- Repackager/Relabeler, where a repackager is a firm that packages finished devices from bulk or

repackages devices made by manufacturer into different containers, without modifying the device or changing its intended use, while a relabeler is a firm that changes the content of labelling from original manufacturer, distributing the device under its own name, not merely adding it;

- Reprocessor of Single Use Device, which is a firm that modifies a single-use device, previously used on a patient, for more than one use;
- Complaint File Establishment, which is a firm that maintains complaint files according to 21 CFR 820.198;
- Foreign Exporter, which is a foreign firm that exports, or offer for export, to the United States devices that are manufactured, prepared, propagated, compounded, or processed in a foreign country, including those originally manufactured in the United States;
- Foreign Private Label Distributor, which is a foreign firm that exports devices manufactured and owned by another party under its own name and under a private label agreement.

As shown in Table 18, most of the medical devices are filed to the FDA by a manufacturer, followed by specification developers and contract manufacturers. Only a few devices have been filed by remanufacturers or foreign private label distributors.

| | 510(k) | DE NOVO | PMA |
|---|---|---|---|
| **Manufacturer** | 46,265 | 253 | 40,156 |
| **Remanufacturer** | 11 | 0 | 0 |
| **Specification Developer** | 8,929 | 49 | 0 |
| **Contract Manufacturer** | 6,389 | 19 | 0 |
| **Contract Sterilizer** | 2,718 | 17 | 0 |
| **Repackager/Relabeler** | 3,372 | 10 | 0 |
| **Reprocessor of Single Use Device** | 232 | 0 | 0 |
| **Complaint File Establishment** | 1,737 | 4 | 0 |
| **Foreign Exporter** | 2,952 | 21 | 0 |
| **Foreign Private Label Distributor** | 22 | 0 | 0 |

Table 18. Number of medical devices by FDA pathway and role of the applicant firm

**Section 4. The features of recalled medical devices**

According to the FDA regulation, a recall is a method of removing or correcting products that are in violation of laws administered by the FDA. In our sample, FDA recorded data on 30,033 recalled devices, indicating an incidence of recalls equal to 26.54 percent.

Recalls are usually conducted voluntarily by the recalling firm (usually, the applicant firm), which carries out its responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. In these cases, the applicant firm is required to immediately notify the FDA. In rare instances, where the applicant fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the applicant.

The FDA conducts an evaluation of the health hazard presented by a product being recalled or considered for recall. On the basis of this evaluation, the FDA will assign the recall a classification to indicate the relative degree of health hazard of the product being recalled or considered for recall, assigning the recall with one of the following three Classes:

I. A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death;
II. A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote;
III. A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

The distribution of recalls by Classes and FDA pathways is presented in Table 19. The most severe recalls, those assigned to Class I, represent a minority, equal to 4.6 percent in 510(k) and De Novo medical devices. In the case of PMA devices, this incidence is larger, but the assignment of recalls to each PMA device is more questionable, especially because FDA data do not allow to univocally assign a recall to specific PMA Supplement devices. To overcome this limitation, we assign a recall to all the Supplement devices that have been filed before the termination of the recall.

| | I | II | III | Total |
|---|---|---|---|---|
| **510(k)** | 385 | 7,445 | 473 | 8,303 |
| **DE NOVO** | 1 | 21 | 4 | 26 |
| **PMA** | 3,224 | 17,390 | 1,090 | 21,704 |
| **Total** | 3,610 | 24,856 | 1,567 | 30,033 |

Table 19. Number of medical device recalls by FDA pathway and recall class

The applicant firm develops a recall strategy that will specify the level in the distribution chain to which the recall is to extend (consumer or user, retail, and/or wholesale level), the need for a public warning (through national/local general/specialized news media), and the effectiveness checks to verify that all consignees have received the recall letter and have taken appropriate action. In general, a recall strategy implies one of the following actions:

- Correction, which means repair, modification, adjustment, relabelling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location;
- Removal, which means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

The FDA will review the adequacy of a proposed recall strategy and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy. The applicant firm is requested to submit periodic recall status reports to the FDA.

A recall could be characterized by different statuses:

- Open, when the correction and/or removal of recalled medical devices is still on-going;
- Completed, when the applicant firm has completed the correction and/or removal of recalled medical devices, but the FDA is still reviewing the process;
- Terminated, when the FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been

made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the FDA to the recalling firm.

The status of recalls that started from 2000 to 2022, as registered on 01/01/2024, is presented in Table 20. While the majority of recalls were terminated, a small minority of them were completed but not terminated by the FDA.

| | 510 | DE NOVO | PMA | Total |
|---|---|---|---|---|
| Open | 1,059 | 7 | 11,196 | 12,262 |
| Completed | 109 | 0 | 992 | 1,101 |
| Terminated | 7,135 | 19 | 9,516 | 16,670 |

Table 20. Status of recalls on 01/01/2024

The duration of a recall process could be evaluated by analysing the duration of the Terminated and Completed recalls, which is presented in Table 21. The average duration of a recall is higher for PMA devices, equal to almost 5 years, and 510(k) devices, larger than 3 years, while it is shorter than 2 years for De Novo devices. For 510(k) and De Novo devices most recall processes end within 2 years, while more than one third of the recalls of PMA devices last more than 5 years.

| | Mean | Coeff. Var. | <1 year | <2 years | <3 years | <4 years | <5 years | >5 years |
|---|---|---|---|---|---|---|---|---|
| **510(k)** | 1,140.36 | 1.01 | 24.97% | 24.50% | 15.61% | 9.66% | 6.13% | 19.12% |
| **DE NOVO** | 675.37 | 0.73 | 36.84% | 26.32% | 15.79% | 10.53% | 10.53% | 0.00% |
| **PMA** | 1,723.06 | 0.95 | 17.89% | 14.89% | 15.06% | 10.36% | 7.75% | 34.04% |

Table 21. Duration of the recall process by FDA pathway

The incidence of product recalls strongly depends on the Regulation of the medical devices. As shown in Table 22, some Regulations, such as “General Hospital”, “Toxicology”, “Neurology”, and “Clinical Chemistry” are characterized by a very large percentage of medical devices affected by at least one recall, especially when focusing on PMA devices.

| | 510(k) | | DE NOVO | | PMA | |
|---|---|---|---|---|---|---|
| | MDs | % | MDs | % | MDs | % |
| **Anesthesiology** | 398 | 14.69% | 0 | 0.00% | 82 | 40.59% |
| **Cardiovascular** | 1,191 | 13.30% | 1 | 3.70% | 12,678 | 57.23% |
| **Clinical Chemistry** | 553 | 17.39% | 4 | 16.00% | 807 | 77.08% |
| **Dental** | 230 | 3.76% | 0 | 0.00% | 131 | 53.69% |
| **Ear, Nose, & Throat** | 59 | 7.19% | 0 | 0.00% | 385 | 53.77% |
| **Gastroenterology & Urology** | 616 | 14.41% | 1 | 2.78% | 1,284 | 66.46% |
| **General & Plastic Surgery** | 684 | 8.49% | 4 | 11.43% | 767 | 37.56% |
| **General Hospital** | 595 | 9.61% | 1 | 6.25% | 554 | 90.82% |
| **Hematology** | 195 | 20.31% | 1 | 16.67% | 0 | 0.00% |
| **Immunology** | 152 | 14.43% | 3 | 11.54% | 244 | 35.26% |
| **Microbiology** | 198 | 11.71% | 5 | 9.43% | 526 | 22.36% |
| **Molecular Genetics** | 0 | 0.00% | 1 | 16.67% | 0 | 0.00% |
| **Neurology** | 319 | 10.03% | 2 | 5.26% | 1,862 | 82.35% |
| **Obstetrics/Gynecology** | 99 | 5.42% | 1 | 6.67% | 169 | 31.77% |
| **Ophthalmic** | 138 | 9.31% | 1 | 6.67% | 1,000 | 39.97% |
| **Orthopedic** | 1,407 | 12.58% | 0 | 0.00% | 804 | 45.40% |
| **Pathology** | 1 | 5.26% | 0 | 0.00% | 289 | 33.64% |
| **Physical Medicine** | 103 | 5.32% | 1 | 20.00% | 3 | 30.00% |
| **Radiology** | 1,269 | 15.83% | 0 | 0.00% | 103 | 48.13% |
| **Toxicology** | 96 | 10.00% | 0 | 0.00% | 16 | 88.89% |
| **Total** | 8,303 | 11.43% | 26 | 7.12% | 21,704 | 54.05% |

Table 22. Number and percentage of medical device recalls by FDA pathway and Regulation

The number of applicant firms whose medical devices have been affected by recalls is shown in Table 23, and it corresponds to more than 13 percent of the total number of applicant firms. Since the incidence of recalls on the total number of medical devices is equal to 26.54 percent, this means that the most productive firms are generally affected by a larger number of recalls than less productive firms.

| | 510(k) | DE NOVO | PMA | Total MDs |
|---|---|---|---|---|
| **Applicants** | 1,771 | 24 | 165 | 1,856 |
| **Countries** | 38 | 5 | 16 | 39 |

Table 23. Number of applicant firms and countries affected by recalls by FDA pathway

Indeed, as shown in Table 24, the incidence of recalls in the 25 most productive firms is very high, especially for the three most productive ones: Medtronic, Boston Scientific, and Abbott. Nevertheless, the share of recalls is not directly correlated to the number of medical devices developed by the firms, as

demonstrated by the small incidence of recalls registered for firms, such as Artuma Holding gmbh and Edwards Lifesciences.

| | 510 | DE NOVO | PMA | Total |
|---|---|---|---|---|
| **Medtronic** | 15.20% | 25.00% | 73.24% | 67.29% |
| **Boston Scientific** | 23.62% | 0.00% | 60.05% | 56.79% |
| **Abbott** | 21.85% | 0.00% | 56.66% | 53.68% |
| **Johnson & Johnson** | 17.25% | 0.00% | 52.76% | 38.59% |
| **Artuma Holding gmbh** | 20.73% | 12.50% | 17.56% | 18.45% |
| **Siemens ag** | 29.26% | 0.00% | 35.28% | 31.14% |
| **Stryker** | 20.55% | 0.00% | 52.50% | 24.00% |
| **Edwards Lifesciences** | 22.06% | 0.00% | 20.26% | 20.45% |
| **GE Healthcare** | 37.94% | 0.00% | 61.90% | 39.46% |
| **W.L. Gore & Associates, inc.** | 6.45% | 0.00% | 53.77% | 50.45% |
| **Biotronik se & co. kg** | 0.00% | 0.00% | 53.70% | 49.83% |
| **Koninklijke Philips n.v.** | 32.35% | 0.00% | 52.00% | 34.69% |
| **Biomet** | 27.35% | 0.00% | 64.68% | 37.03% |
| **Alcon ag** | 19.74% | 0.00% | 42.05% | 39.84% |
| **Zimmer Biomet** | 29.61% | 0.00% | 62.11% | 36.78% |
| **Becton, Dickinson & Co.** | 19.36% | 0.00% | 28.23% | 22.06% |
| **Integra Lifesciences** | 19.48% | 0.00% | 43.33% | 33.64% |
| **Cook Medical** | 12.20% | 33.33% | 40.52% | 18.98% |
| **Smith & Nephew plc** | 17.91% | 0.00% | 44.53% | 23.27% |
| **CR Bard** | 23.13% | 0.00% | 33.62% | 27.54% |
| **Hologic** | 9.24% | 0.00% | 23.65% | 20.24% |
| **St. Jude Medical** | 8.47% | 0.00% | 58.31% | 40.52% |
| **Synthes** | 26.48% | 0.00% | 49.53% | 31.82% |
| **The Cooper Companies, inc.** | 15.07% | 0.00% | 31.22% | 28.60% |
| **Microport Scientific Corporation** | 2.38% | 0.00% | 75.00% | 68.04% |

Table 24. Percentage of recalled medical devices filed by the top 25 applicant firms by FDA pathway

The incidence of recalls in the different regions where the applicant firms are headquartered is unevenly distributed, as shown in Table 25, with a higher incidence of recalls in U.S. and Anglo-Saxon firms, followed by EU and other European ones.

The analysis of recall incidence at the country level, presented in Table 26, shows that the value registered for U.S. firms is overcome only by firms headquartered in Cayman Islands and Austria.

| | 510(k) | DE NOVO | PMA |
|---|---|---|---|
| **African countries** | 6.25% | 0.00% | 0.00% |
| **Anglo-Saxon countries** | 9.90% | 4.17% | 52.04% |
| **China** | 2.04% | 0.00% | 0.00% |
| **East Asian countries** | 8.69% | 50.00% | 28.59% |
| **European Union** | 13.70% | 2.33% | 43.11% |
| **Indian countries** | 0.00% | 0.00% | 0.00% |
| **Israel** | 6.85% | 0.00% | 0.00% |
| **Latin American countries** | 1.35% | 0.00% | 0.00% |
| **Middle East countries** | 0.00% | 0.00% | 0.00% |
| **Other European countries** | 15.58% | 15.38% | 30.99% |
| **Southeast Asian countries** | 1.29% | 0.00% | 0.00% |
| **United States of America** | 13.07% | 7.72% | 57.76% |

Table 25. Percentage of recalled medical devices in each geographical region by FDA pathway

| | 510(k) | DENOVO | PMA | Total MDs |
|---|---|---|---|---|
| **United States** | 13.07% | 7.72% | 57.76% | 32.69% |
| **Germany** | 15.63% | 0.00% | 46.58% | 24.02% |
| **Switzerland** | 16.30% | 15.38% | 31.00% | 23.83% |
| **China** | 1.84% | 0.00% | 0.00% | 1.84% |
| **Japan** | 13.53% | 50.00% | 28.59% | 16.61% |
| **United Kingdom** | 12.25% | 0.00% | 63.41% | 22.03% |
| **South Korea** | 1.53% | 0.00% | 0.00% | 1.53% |
| **Taiwan** | 2.54% | 0.00% | 0.00% | 2.54% |
| **Israel** | 6.85% | 0.00% | 0.00% | 6.18% |
| **Italy** | 8.62% | 0.00% | 10.03% | 8.90% |
| **France** | 7.93% | 0.00% | 50.94% | 10.96% |
| **Netherlands** | 24.50% | 0.00% | 43.91% | 28.50% |
| **Canada** | 8.37% | 0.00% | 26.47% | 10.89% |
| **Sweden** | 16.17% | 0.00% | 24.05% | 17.85% |
| **Australia** | 5.36% | 50.00% | 21.51% | 13.01% |
| **Malaysia** | 1.36% | 0.00% | 0.00% | 1.36% |
| **Denmark** | 10.88% | 0.00% | 57.82% | 22.72% |
| **Ireland** | 11.32% | 16.67% | 74.49% | 23.11% |
| **Cayman Islands** | 1.30% | 0.00% | 75.00% | 63.00% |
| **Spain** | 9.71% | 0.00% | 0.00% | 9.65% |
| **Belgium** | 14.20% | 0.00% | 0.00% | 14.07% |
| **Austria** | 7.89% | 0.00% | 79.29% | 41.98% |
| **India** | 0.00% | 0.00% | 0.00% | 0.00% |
| **Finland** | 8.72% | 0.00% | 0.00% | 8.68% |
| **Singapore** | 0.60% | 0.00% | 0.00% | 0.59% |

Table 26. Percentage of recalled medical devices filed by the top 25 countries by FDA pathway