NEGATIVE: PRE-MARKET/510K REFORM

By Joseph "Coach Graham"

Affirmative proposals to significantly reform or eliminate the FDA's 510(k) clearance pathway in favor of more stringent requirements, such as mandatory randomized controlled trials (RCTs) or defaulting to the Premarket Approval (PMA) process. Such proposals often assume the current system is dangerously lax or fails to ensure patient safety. AFF seems to prefer a perfectly safe system with no harms over an approval process that balances benefit and risk. This brief explains how the FDA already exercises flexible, risk-based oversight tailored to device type and clinical context. It demonstrates that most recalls are due to factors unrelated to the approval pathway, that the PMA process itself carries substantial risks, and that innovation, patient access, and democratic transparency would be harmed by the Affirmative's plan. This brief equips Negative teams with arguments to counter claims about 510(k) inadequacy, prove that current reforms are already underway, and show that AFF proposals would slow innovation, delay patient access to life-saving treatments, and damage the integrity of the regulatory process.

NEGATIVE: PMA/510K REFORM

NEG PHILOSOPHY

1. FDA Advances Public Health

Speeding innovation improves public health

FDA, Accessed 2025 (The Food and Drug Administration is a U.S. federal agency) "What We Do" 21 Nov, 2023. https://www.fda.gov/about-fda/what-we-do (accessed 16 May 2025)

FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

BACKGROUND

1. Device Classifications

Class 1 Devices

Nextern Marketing, 2024 (Nextern is a collaborative medical device company. We bring an unmatched core competence in medical device product design and development through manufacturing as a leverageable asset to collaborators, who are focused on accelerating the commercial side of their businesses.) "Medical Device Classes Explained: What They Mean for Regulatory Approval" 9 Sep, 2024. https://nextern.com/2024/09/09/medical-device-classes-explained-what-they-mean-for-regulatory-approval/ (accessed 16 May 2025)

Class I medical devices are the simplest and present the lowest risk to patients and users. These devices are generally designed for basic, non-invasive procedures and are commonly used in various healthcare settings. The FDA defines Class I devices as: "Devices that pose minimal potential harm to the user and are often simple in design." Examples of Class I Medical Devices: Bandages; Examination gloves; Handheld surgical instruments; Stethoscopes; Manual toothbrushes. Regulatory Pathway for Class I Devices: Class I devices are subject to the least regulatory control. Most of these devices are exempt from the FDA's premarket notification (510(k)) process, meaning manufacturers do not need to submit extensive data to demonstrate safety and effectiveness. Instead, manufacturers must comply with general controls, which include requirements for proper labeling, registration with the FDA, and adherence to good manufacturing practices. Despite the lower regulatory burden, manufacturers of Class I devices must ensure that their products are safe for use and meet all applicable standards. About 47% of medical devices fall under this category, reflecting the large number of simple, low-risk products that are essential in everyday healthcare.

Class 2 Devices

Nextern Marketing, 2024 (Nextern is a collaborative medical device company. We bring an unmatched core competence in medical device product design and development through manufacturing as a leverageable asset to collaborators, who are focused on accelerating the commercial side of their businesses.) "Medical Device Classes Explained: What They Mean for Regulatory Approval" 9 Sep, 2024. https://nextern.com/2024/09/09/medical-device-classes-explained-what-they-mean-for-regulatory-approval/ (accessed 16 May 2025)

Technology that falls under Class II is more complex and carries a moderate risk compared to Class I devices. These devices are often essential in medical settings, but they do not usually support or sustain life. The FDA defines Class II devices as: "Devices that require more regulatory controls to provide reasonable assurance of the device's safety and effectiveness. These devices generally present a moderate risk to the patient." Class II devices often have a greater impact on patient health and may be intended for more long-term use. As a result, they require a higher level of scrutiny, including additional regulatory controls such as special labeling requirements, mandatory performance standards, and post-market surveillance. Examples of Class II Medical Devices: Powered Wheelchairs; Surgical Drills; Blood Pressure Monitors; Catheters; Contact Lenses; Digital Thermometers; Regulatory Pathway for Class II Devices. Unlike Class I devices, which are largely exempt from premarket submissions, Class II devices usually require a 510(k) submission to the FDA. This premarket notification process ensures that the device is safe and effective by demonstrating that it is substantially equivalent to an existing device. Approximately 43% of medical devices fall under this category, and most must undergo this submission process to be legally marketed. While Class II devices do not typically require the more stringent premarket approval (PMA) process the 510(k) process involves rigorous testing and documentation to prove safety and effectiveness. And in some cases if similarity to a predicate device cannot be proven, a Premarket Approval is required.

Class 3 Devices

Nextern Marketing, 2024 (Nextern is a collaborative medical device company. We bring an unmatched core competence in medical device product design and development through manufacturing as a leverageable asset to collaborators, who are focused on accelerating the commercial side of their businesses.) "Medical Device Classes Explained: What They Mean for Regulatory Approval" 9 Sep, 2024. https://nextern.com/2024/09/09/medical-device-classes-explained-what-they-mean-for-regulatory-approval/ (accessed 16 May 2025)

Class III medical devices are the most complex and carry the highest risk to patient safety. These devices are often life-sustaining, life-supporting, or implanted, and therefore, require the strictest regulatory controls. The FDA defines Class III devices as: "Devices that usually sustain or support life, are implanted, or present a potential unreasonable risk of illness or injury." Class III devices undergo the most rigorous scrutiny by the FDA due to the potential risks they pose. They often are cutting-edge medical technology, with the potential to save or significantly improve lives. Examples of Class III Medical Devices: Implantable Pacemakers; Heart Valves; Implantable Defibrillators; Cochlear Implants; Deep Brain Stimulators; Regulatory Pathway for Class III Devices. Unlike Class I & II devices, Class III devices are almost always required to go through the premarket approval (PMA) process. The PMA process is the most rigorous type of application required by the FDA. It involves a thorough review of clinical data to support the device's safety and effectiveness. Premarket Approval (PMA): The PMA process requires manufacturers to submit extensive clinical trial data, technical specifications, and detailed reports on the device's design, manufacturing, and testing processes. The FDA rigorously reviews this data to ensure the device meets the necessary safety and efficacy standards. Post-Market Surveillance: Even after approval, Class III devices are often subject to post-market surveillance to monitor their long-term safety and effectiveness. This may include mandatory reporting of adverse events, additional studies, and ongoing regulatory oversight. In many cases additional submissions may be required even years after approval. This would occur in the case of new indications of use, significant device modifications or emerging safety concerns that would warrant new studies to reassess the device as safe and effective.

INHERENCY

1. Status Quo Reforms

2023 Guidance Published

FDA, 2023 (The Food and Drug Administration is a U.S. federal agency) "FDA Continues to Take Steps to Strengthen the Premarket Notification [510(k)] Program - Program Updates" 29 May, 2024. https://www.fda.gov/medical-devices/510k-clearances/fda-continues-take-steps-strengthen-premarket-notification-510k-program-program-updates (accessed 16 May 2025)

The FDA Continues to Modernize the 510(k) Program. In September 2023, the FDA released three draft guidances that, when finalized, are intended to provide updated recommendations on specific aspects of the 510(k) Program. The three draft guidances are: Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission; Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions; Evidentiary Expectations for 510(k) Implant Devices. These draft guidances are informed by a 2019 request for public feedbackExternal Link Disclaimer to continue to modernize the 510(k) Program while promoting patient safety. The issuance of these draft guidance documents signifies new steps the FDA is taking to further modernize the 510(k) Program. These guidances are not currently for implementation, but when finalized, may help improve the safety and effectiveness of devices in the 510(k) Program over time.

Best Practices for Selecting a Predicate (legally marketed benchmark medical device) Device

FDA, 2023 (The Food and Drug Administration is a U.S. federal agency) "FDA Continues to Take Steps to Strengthen the Premarket Notification [510(k)] Program - Program Updates" 29 May, 2024. https://www.fda.gov/medical-devices/510k-clearances/fda-continues-take-steps-strengthen-premarket-notification-510k-program-program-updates (accessed 16 May 2025)

The FDA wrote a draft guidance outlining recommended best practices for selecting a predicate device. The factors include that the predicate device: Was cleared using well-established methods; Meets or exceeds expected safety and performance; Does not have unmitigated use-related or design-related safety issues, and; Is not associated with a design-related recall. The draft guidance explains how use of these best practices is expected to benefit manufacturers, the FDA, and public health, and provides examples of how to apply these best practices. The FDA believes use of these best practices outlined in this draft guidance, once finalized, will encourage the evolution of safer and more effective medical devices in the 510(k) Program over time.

Clinical Data in 510k submissions

FDA, 2023 (The Food and Drug Administration is a U.S. federal agency) "FDA Continues to Take Steps to Strengthen the Premarket Notification [510(k)] Program - Program Updates" 29 May, 2024. https://www.fda.gov/medical-devices/510k-clearances/fda-continues-take-steps-strengthen-premarket-notification-510k-program-program-updates (accessed 16 May 2025)

Through this draft guidance, the FDA provides transparency on when the FDA recommends manufacturers submit clinical data in their 510(k) submission. Specifically, this draft guidance clarifies certain situations when clinical data may or may not be needed to support a 510(k) submission, as initially described in the 510(k) Program guidance. It also provides examples to illustrate when clinical data may or may not be needed in a 510(k) submission. The FDA believes these recommendations, once finalized, will enhance predictability, consistency, and transparency in the use of clinical data in 510(k) submissions and lead to the appropriate data the FDA needs to make substantial equivalence determinations to assure the safety and effectiveness of devices.

Evidentiary Expectations for Implant Devices

FDA, 2023 (The Food and Drug Administration is a U.S. federal agency) "FDA Continues to Take Steps to Strengthen the Premarket Notification [510(k)] Program - Program Updates" 29 May, 2024. https://www.fda.gov/medical-devices/510k-clearances/fda-continues-take-steps-strengthen-premarket-notification-510k-program-program-updates (accessed 16 May 2025)

This draft guidance is expected to enhance predictability for sponsors in preparing 510(k) submissions for implants and promote consistency in review of implants through the 510(k) Program. The draft guidance is intended to: Serve as a primary resource on expectations for all 510(k) implant devices, generally, while device-specific guidances provide further specificity for a given device type; Assist industry in design and execution of appropriate performance testing to support 510(k) submissions for implant devices; Provide recommendations for content and labeling to include in 510(k) submissions for implant devices, and; Convey that the FDA considers the patient experience to be paramount in improving implant device safety, and encourages the collection, analysis, and integration of patient experience data for implants to support 510(k) submissions for those devices. This draft guidance discusses review considerations that apply to all implanted devices reviewed in the 510(k) Program. The FDA expects this guidance, once finalized, will enhance transparency, consistency, and predictability of the 510(k) premarket review process for implanted medical devices.

2. Status Quo Flexible and Balanced

FDA standards promote probable benefits over probable risks

FDA in its Guidance for Industry and Food and Drug Administration Staff, 2023 (The Food and Drug Administration is a U.S. federal agency) "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions" 30 Aug, 2019. https://www.fda.gov/media/115672/download (accessed 16 May 2025)

This guidance document describes the Food and Drug Administration's (FDA or Agency) current approach to considering uncertainty in making benefit-risk determinations to support FDA premarket decisions for medical device premarket approval applications (PMAs), De Novo requests, and humanitarian device exemption (HDE) applications. FDA believes the approach described in this guidance promotes the public health by helping patients have timely access to new medical devices meeting the applicable statutory standard for safety and effectiveness, such that probable benefits of device use outweigh the probable risks and the device will provide clinically significant results in a significant portion of the target population, based on the totality of the valid scientific evidence.

3. Status Quo Regards Risk

FDA standards promote probable benefits over probable risks

FDA in its Guidance for Industry and Food and Drug Administration Staff, 2023 (The Food and Drug Administration is a U.S. federal agency) "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions" 30 Aug, 2019. https://www.fda.gov/media/115672/download (accessed 16 May 2025)

Before making a decision that is likely to affect product availability, FDA may also consider the impact on the patient if the device is available or not available, whether the issue affects a single manufacturer or the whole industry, and patient or caregiver preference for availability. Specific benefit-risk assessments should be viewed in the larger context that includes consideration of the additional factors described in Section IV.C, but generally, if the benefit-risk assessment indicates high benefit to patients with little risk, FDA may be more likely to decide that it is appropriate for patients to have access to a nonconforming device while the long-term corrective action is taken if appropriate alternative treatments are not available. Alternatively, if the benefit-risk assessment indicates low benefit to patients with high risk, FDA would be more likely to take action to limit product availability.

4. Alternative Pathways

De Novo Classification rarely used pathway

Mateo Aboy, Cristina Crespo & Ariel Stern, 2024 (The Food and Drug Administration is a U.S. federal agency) "Beyond the 510(k): The regulation of novel moderate-risk medical devices, intellectual property considerations, and innovation incentives in the FDA's De Novo pathway" 8 Feb, 2024. https://www.nature.com/articles/s41746-024-01021-y (accessed 16 May 2025) [brackets added for clarity]

On September 9, 2019, it issued another guidance document on the Acceptance Review for De Novo Classification Requests Guidance to further support the De Novo process as a pathway to classify novel medical devices without a legally marketed predicate device. This alternative pathway is now available to both (1) applicants receiving a NSE **[Not Substantially Equivalent]** determination (i.e., instead of resulting in an automatic class III classification and associated need for a PMA application), and (2) applicants claiming that there is no legally marketed device upon which to base a determination of SE **[Substantial Equivalence]** (without having to first submit a 510(k)). The latter option, in effect, created a third regulatory pathway (direct submission of a De Novo Classification request) for medical device applicants.

De Novo Use Increasing

Mateo Aboy, Cristina Crespo & Ariel Stern, 2024 (The Food and Drug Administration is a U.S. federal agency) "Beyond the 510(k): The regulation of novel moderate-risk medical devices, intellectual property considerations, and innovation incentives in the FDA's De Novo pathway" 8 Feb, 2024. https://www.nature.com/articles/s41746-024-01021-y (accessed 16 May 2025) [brackets added for clarity]

Prior to 2013, all De Novo classifications resulted from a failure to obtain 510(k) clearance for the device due to a NSE determination. Since the 2017 publication of the FDA De Novo guidance this trend has almost reversed. From 2017 to August 2023 (n = 180), 97.22% of the applications were "direct" De Novo classification requests; the overwhelming majority of De Novo applicants are now opting into this regulatory pathway deliberately.

De Novo Offers balance between 510k review timeline and PMA

Mateo Aboy, Cristina Crespo & Ariel Stern, 2024 (The Food and Drug Administration is a U.S. federal agency) "Beyond the 510(k): The regulation of novel moderate-risk medical devices, intellectual property considerations, and innovation incentives in the FDA's De Novo pathway" 8 Feb, 2024. https://www.nature.com/articles/s41746-024-01021-y (accessed 16 May 2025) [brackets added for clarity]

The mean decision time for De Novo requests over the period of observation was 338 days (median = 309 days). For comparison, the FDA mean review times were 150 days for 510(k)s and 399 for PMA devices over a similar period of time. Thus, on average, De Novo decision times were 2.3-fold longer than the FDA 510(k) review times and were roughly 15% shorter than contemporaneous PMA review times. However, as shown in Fig. 2, De Novo review times varied substantially. Decision times for De Novo submissions ranged from <1 month to over 30 months. The heterogeneity in decision times may not be uniform across product types, and could be due to higher submission rates or fewer resources associated with certain FDA device classification panels for the different medical specialties. Among the fastest De Novo decision times in our sample were Apple's De Novo requests for the Apple Watch "ECG App" and the "Irregular Rhythm Notification Feature" (28 and 33 days, respectively).

SIGNIFICANCE

1. PMA risks

[STUDY] PMA 2.7x recall hazard compared to 510(k) process

Jonathan R Dubin, Stephen D Simon, Kirsten Norrell, Jacob Perera, Jacob Gowen, Akin Cil, 2021 (Authors represent the Department of Orthopedic Surgery, University of Missouri–Kansas City; Department of Orthopedic Surgery, Truman Medical Center, Kansas City, Missouri; Department of Medical and Health Informatics.) "Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017" 6 May, 2021. https://pmc.ncbi.nlm.nih.gov/articles/PMC8103223/ (accessed 16 May 2025)

Question. What is the risk of recall and high-risk recall for devices undergoing US Food and Drug Administration (FDA) 510(k) clearance compared with premarket approval (PMA)? Findings. In this cohort study using the FDA's 510(k) and PMA medical device database, 28,556 devices were reviewed. Although 97% of recalled devices had received 510(k) clearance, devices with PMA had 2.7 times the hazard of recall and 7.3 times the hazard of high-risk recall compared with devices with 510(k) clearance. Meaning. This study suggests that, despite the requirement of clinical trials, high-risk devices approved via PMA were associated with greater safety concerns than previously reported; in addition, most recalls are for 510(k) devices, raising safety issues.

[STUDY] Post PMA "Device Drift"

Andre M Samuel, Vinay K Rathi, Jonathan N Grauer, Joseph S Ross, 2015 (Authors represent the Department of Orthopaedics and Rehabilitation, Yale School of Medicine; Department of Internal Medicine, Yale School of Medicine; Department of Health Policy and Management, Yale School of Public Health.) "How do Orthopaedic Devices Change After Their Initial FDA Premarket Approval?" 19 Nov, 2015. https://pmc.ncbi.nlm.nih.gov/articles/PMC4773325/ (accessed 16 May 2025)

Conclusions. Relatively few orthopaedic devices undergo the FDA PMA process before reaching the market. Orthopaedic surgeons should be aware that high-risk medical devices cleared via the FDA's PMA pathway do undergo considerable postmarket device modification after reaching the market, with potential for design "drift," ie, shifting away from the initially tested and approved device designs.

Clinical Relevance. As the ultimate end-users of these devices, orthopaedic surgeons should be aware that even among high-risk medical devices approved via the FDA's PMA pathway, considerable postmarket device modification occurs. Continued postmarket device monitoring will be essential to limit patient safety risks.

PMA 29% of Class 1 Recalls, and some PMA approvals required NO clinical trials. Some trials have no active control.

Michael Walter, 2023 (Healthcare journalist.) Cardiovascular Business. "Most recalled cardiovascular devices gained FDA approval with little to no clinical evidence" 23 Sep, 2023. https://cardiovascularbusiness.com/topics/healthcare-management/healthcare-policy/most-recalled-cardiovascular-devices-gained-fda-approval-little-no-clinical-evidence (accessed 16 May 2025)

Kadakia et al. explored data from a total of 137 Class I recall events that affected 157 different cardiovascular devices. A majority (71.3%) of devices gained approval through the FDA's 510(k) pathway, meaning the manufacturer had to prove it was similar to devices already being marketed in the United States. The other 28.7% of devices were approved using the FDA's premarket approval (PMA) pathway, which requires premarket clinical evidence to be gathered by the manufacturer and sent to the FDA for review. However, 55.6% of those devices were PMA supplements and not original PMA submissions, meaning little (and sometimes no) clinical testing was required. "Even when premarket clinical testing was conducted, evidence was usually generated from a single nonrandomized, unblinded clinical trial using surrogate measures with no active control. In other words, medical devices later recalled due to safety issues often had little clinical evidence supporting their original authorization," the authors wrote.

2. 501(k) necessary

501(k) necessary as novel technologies like AI, and Machine Learning advance

Brian J Miller, William Blanks, Brian Yagi, 2023 (Authors represent the Division of Hospital Medicine, The Johns Hopkins University School of Medicine; The Johns Hopkins Carey Business School; American Enterprise Institute; and West Virginia University School of Medicine.) "The 510(k) Third Party Review Program: Promise and Potential" 29 Aug, 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC10465388/ (accessed 16 May 2025)

Every year, the Food and Drug Administration (FDA) clears approximately 3,000 medical devices for marketing via the 510(k) pathway. These constitute 99% of all devices approved for human use and includes the premarket review of many devices incorporating newer technology such as artificial intelligence (AI), machine learning (ML), and other software. As the complexity of these novel technologies and the number of applications is expected to increase in the coming years, statutory changes such as the 2016 21st Century Cures Act, regulations, and guidance documents have increased both the volume and complexity of device review. Thus, the ability to streamline the review of less complex, low-to-moderate risk devices through the 510(k) pathway will maximize the FDA's capability to address other important, future-oriented regulatory questions.

3. Reasons for Recall

FDA Recalls are not fault of approval process

Paul Citron, 2011 (Paul Citron is a founding member of the American Institute for Medical and Biological Engineering, retired from Medtronic, Inc., in 2003 after a 32-year career. Issues in Science and Technology is a quarterly journal published by the National Academy of Sciences and Arizona State University. The journal is a forum for discussion of public policy related to science and technology.) Issues in Science & Technology Vol. XXVII, No. 3, Spring 2011 "Medical Devices: Lost in Regulation" Spring 2011. https://issues.org/p_citron/ (accessed 16 May 2025)

It is presumed, incorrectly, that a lax approval process is responsible. In most instances, however, the actual cause of a recall is outside the scope of the approval process. The most frequent causes of recalls are isolated lot-related subcomponent failure; manufacturing issues such as operator error, processing error, or in-process contamination; latent hardware or software issues; and packaging or labeling issues. In addition, company communications that describe incorrect and potentially dangerous procedures used by some medical personnel are also considered a recall, even though the device is not faulty. Face-saving implementation of new and more burdensome clinical trial requirements, often called added rigor by the FDA, is an ineffective and wrong answer to such problems.

4. Producer Quality Required

SE letter is not an approval. 501(k) clearances must maintain FDA Quality Regulations

Oriel Stat A Matrix, 2023 (Oriel STAT A MATRIX is the oldest quality improvement training and consulting firm in the US. Medical device clients have come to trust us for our deep subject matter expertise and proven ability to deliver long-term results. Today, we carry on that tradition of excellence along with several other life sciences regulatory consultancies that now comprise ELIQUENT Life Sciences..) "The FDA 510(k) Process: Setting the Stage for a Successful Submission and Faster Approval" 16 Oct, 2023.https://www.orielstat.com/blog/fda-510k-process/ (accessed 16 May 2025)

The substantially equivalent (SE) letter is not an approval by FDA, but it serves the same purpose because it legally authorizes the holder to market the device in the US. Unlike other countries, no certificate will be issued by FDA but your SE letter will be posted on the FDA website along with your 510(k) summary. Your 510(k) clearance will not expire and is valid until you make changes to the intended use, alter the indications for use, or change technological characteristics. At the time your 510(k) clearance letter is issued, you are expected to be in full compliance with the FDA Quality System Regulation (21 CFR Part 820) when distribution of the device begins in the US.

5. Classification System

Risk determines how devices are classified

BMP Medical, Accessed May 2025 (BMP Medical (A Biomedical Polymers Company), we provide OEM Contract Manufacturing Services for the medical device industry; producing highly precise plastic consumables used in devices and diagnostic kits.) "What's the Difference Between the FDA Medical Device Classes?" No Publication Date. Accessed 16 May, 2025. https://bmpmedical.com/whats-difference-fda-medical-device-classes-2/ (accessed 16 May 2025)

Regulatory policy for medical devices follows a three-tiered classification system. They are, simply, Class I, II, and III. Though the policy is straightforward enough, there are challenges. The FDA has classified around 1,700 different generic types of devices. These are grouped into 16 medical panels, which are then assigned to one of the three regulatory classes to determine the level of control necessary to assure the safety and effectiveness of the device. What then, determines if your medical device is Class I, II, or III? The answer is risk. Each medical device is classified by the risks associated with the device. The higher numbered class, the greater the regulatory control, which further defines the regulatory requirements for a general device type. Classification is determined not only by what risk the device poses to the patient and/or the user, but also the intended use of the device along with any specialized indications for its use. For example, a scalpel may have the intended use to cut tissue of a patient, but a manufacturer may have a specialized scalpel specifically designed to make incisions in the cornea.

Benefits must balance risk. "Perfect is the enemy of the good."

Paul Citron, 2011 (Paul Citron is a founding member of the American Institute for Medical and Biological Engineering, retired from Medtronic, Inc., in 2003 after a 32-year career. Issues in Science and Technology is a quarterly journal published by the National Academy of Sciences and Arizona State University. The journal is a forum for discussion of public policy related to science and technology.) Issues in Science & Technology Vol. XXVII, No. 3, Spring 2011 "Medical Devices: Lost in Regulation" Spring 2011. https://issues.org/p_citron/ (accessed 16 May 2025)

The FDA has a very legitimate role to play in ensuring that new technologies are sufficiently safe and effective for patient use. This is a relative, not absolute, standard. Benefits must be balanced against risk. As practiced today, the regulatory process is unbalanced at the expense of innovations that could help patients. Current FDA processes for the approval of medical device innovations need to be reengineered to balance the quest for avoidance of possible harms with the potential for helping today's seriously ill patients. The agency must also limit the scope of studies to address necessary questions rather than to aspire to scientific elegance and excessive statistical certainty. As Voltaire said, "The perfect is the enemy of the good." The European experience demonstrates that it is possible to make safe and effective new medical devices available to patients much more quickly. Actual clinical experience demonstrates that an excessively cautious and slow regulatory process conflicts with the interests of patients suffering from serious and progressive diseases. They simply don't have the luxury of time.

Class III is the default

Brian J Miller, William Blanks, Brian Yagi, 2023 (Authors represent the Division of Hospital Medicine, The Johns Hopkins University School of Medicine; The Johns Hopkins Carey Business School; American Enterprise Institute; and West Virginia University School of Medicine.) "The 510(k) Third Party Review Program: Promise and Potential" 29 Aug, 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC10465388/ (accessed 16 May 2025)

Devices seeking marketing authorization after 1976 are by default considered class III and require submission and approval of a PMA. If a manufacturer can demonstrate that a class I or II device is substantially equivalent to a previously marketed device – a predicate device – then the manufacturer can instead file a 510(k) submission (see Fig. 1). A 510(k) submission requires that a company demonstrate that a device has the same intended use and technological characteristics as the predicate device. Alternatively, the manufacturer may demonstrate that the device has the same intended use, but different characteristics that do not raise safety or efficacy questions. In this situation, the FDA will usually request performance data to support the application and will scrutinize the performance study's scientific methods in addition to its findings on safety and efficacy .

Class I, II, & III

BMP Medical, Accessed May 2025 (BMP Medical (A Biomedical Polymers Company), we provide OEM Contract Manufacturing Services for the medical device industry; producing highly precise plastic consumables used in devices and diagnostic kits.) "What's the Difference Between the FDA Medical Device Classes?" No Publication Date. Accessed 16 May, 2025. https://bmpmedical.com/whats-difference-fda-medical-device-classes-2/ (accessed 16 May 2025)

Class I Medical Devices. A Class I medical device are those devices that have a low to moderate risk to the patient and/or user. Today, 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process. If a device falls into a generic category of exempted Class I devices, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, the manufacturer is required to register their establishment and list their generic product with FDA. Examples include enema kits, elastic bandages, manual stethoscopes, and bedpans.

Class II Medical Devices. Class II medical devices are those devices that have a moderate to high risk to the patient and/or user. 43% of medical devices fall under this category. Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits.

Class III Medical Devices. Class III medical devices are those devices that have a high risk to the patient and/or user. These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. They represent 10% of medical devices regulated by the FDA. Examples of Class III devices include implantable pacemakers and breast implants. We hope this was helpful. BMP Medical is an FDA approved original equipment manufacturer of medical devices. In order to ensure approval, as part of our validation services, we advise and assist clients in helping them understand the distinctions between the different medical device classifications.

A/T "Recalls" –92% not serious. Manufacturers liable.

Recalls are categorized for severity. Most are temporary problems as Class II, or slight risk

Searcy Law, 2022 (The partners of Searcy Denney Scarola Barnhart & Shipley have fostered a culture of excellence for more than 45 years. Through a commitment to sharing their wide range of personal and professional experience, our team of Florida lawyers is able to go toe-to-toe against powerful insurance companies and other corporations that put their profit before your safety.) "What Should Patients Know about Medical Device Recalls?" 4 April, 2022. https://www.searcylaw.com/what-should-patients-know-about-medical-device-recalls/ (accessed 17 May 2025)

Medical devices get recalled for different reasons, some of which are more concerning for patients than others. The FDA divides medical device recalls into three classifications:

Class I – Class I recalls are the most serious. With a Class I recall, the FDA has determined that there is a "reasonable chance" that the defective medical device will cause serious health problems or death.

Class II – A Class II recall can mean one of two things. Either (i) the device "may cause a temporary or reversible health problem," or (ii) "there is a slight chance that it will cause serious health problems or death."

Class III – Class III recalls are the least serious. The FDA issues these recalls when a medical device, while defective, is not likely to cause any health problem or injury.

According to FDA data, the substantial majority of medical device recalls (approximately 92 percent) are Class II.

Manufacturer defects are subject to product liability

Searcy Law, 2022 *(The partners of Searcy Denney Scarola Barnhart & Shipley have fostered a culture of excellence for more than 45 years. Through a commitment to sharing their wide range of personal and professional experience, our team of Florida lawyers is able to go toe-to-toe against powerful insurance companies and other corporations that put their profit before your safety.) "What Should Patients Know about Medical Device Recalls?" 4 April, 2022.* https://www.searcylaw.com/what-should-patients-know-about-medical-device-recalls/ *(accessed 17 May 2025)*

Lawsuits involving defective medical devices are governed by the law of product liability. Under this law, manufacturers are "strictly liable" for patients' losses—meaning that proof of negligence is not required. Patients who have defective medical device lawsuits can seek just compensation for their current and future losses. This includes medical expenses, job loss, pain and suffering, and emotional trauma, among others.

SOLVENCY

1. More Resources Necessary

Increasing rigor requires substantially more resources for FDA

Avia M. Dunn, Maya P. Florence, Rachel Turow, Nicole L. Grimm, 2025 *(Skadden, Arps, Slate, Meagher & Flow are a law firm serving clients in litigation, tax, & antitrust.) Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates. "Gauging the Likelihood of Trump Administration FDA Reforms" 22 Jan, 2025.* https://www.skadden.com/insights/publications/2025/01/gauging-the-likelihood-of-trump-administration-fda-reforms *(accessed 16 May 2025)*

Since the implementation of the Medical Device User Fee Amendments (MDUFA) in 2002, FDA's Center for Devices and Radiological Health (CDRH) has substantially increased its oversight of Class II medical devices, including those that reach the market through the 510(k) pathway. Among other reforms, CDRH has implemented a total product life cycle (TPLC) approach, integrating safety and compliance into the initial review process, and has increased transparency of device recalls through an "early alert" system that notifies the public about significant issues that likely will lead to a recall. In addition, FDA reclassified many high-risk Class II devices as Class III following passage of the FDA Safety and Innovation Act in 2012.7 And, in 2023, FDA published three draft guidance documents narrowing the criteria for predicate selection, clarifying the appropriate use of clinical data and explaining evidentiary requirements for implants under 510(k). Further increasing the rigor of the 510(k) process would require substantially more resources due to the volume of 510(k) submissions FDA reviews each year. The most recent MDUFA performance report covering FY 2023 shows that FDA reviewed 3,222 510(k) applications requiring substantive interaction that year, in addition to 3,639 pre-submission packages.

FDA faces persistent staffing challenges for reviews

Brian J Miller, William Blanks, Brian Yagi, 2023 (Authors represent the Division of Hospital Medicine, The Johns Hopkins University School of Medicine; The Johns Hopkins Carey Business School; American Enterprise Institute; and West Virginia University School of Medicine.) "The 510(k) Third Party Review Program: Promise and Potential" 29 Aug, 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC10465388/ (accessed 16 May 2025)

Woven into the background of the aforementioned policy concerns is a persistent, well-documented agency challenge in hiring qualified technical staff to support statutorily-mandated agency review programs. FDA human capital acquisition and retention, the subject of many critical reports, is buttressed by specific hiring authorities and salary flexibility to award relative differential compensation above the standard civil service pay scale to technical experts such as physicians and engineers. Barriers include the high cost of living in the Washington-Baltimore corridor, a geographic location in suburban Maryland with limited mass transit, and a relative dearth of loco-regional industry jobs if workers later wish to transition out of government. Thus, despite the positive, mission-driven nature of FDA regulatory work, talent acquisition remains a significant challenge.

2. Clinical Trials Not Always Necessary

FDA exercises a Flexible, Patient-centric, benefit-risk approach

FDA in its Guidance for Industry and Food and Drug Administration Staff, 2023 (The Food and Drug Administration is a U.S. federal agency) "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions" 30 Aug, 2019. https://www.fda.gov/media/115672/download (accessed 16 May 2025)

To better articulate FDA's policy on its decision-making in various other contexts across the total product lifecycle, including with respect to other types of submissions for devices, FDA has published several guidances that demonstrate a flexible, patient-centric, benefit-risk approach, including the consideration of patient preferences and uncertainty. These guidances, including this Uncertainty guidance, complement one another: for example, the PMA and De Novo Benefit-Risk guidance lists uncertainty as a factor in benefit-risk decisions, while this guidance further clarifies how we determine the appropriate extent of uncertainty for a device. FDA's approach is tailored to the type and intended use of the device and the type of decision we are making. For example, as a general matter, high-risk and innovative moderate-risk devices will typically need clinical evidence to show reasonable assurance of safety and effectiveness, including that the benefits of the device outweigh its risks. However, non-clinical performance data, such as bench studies, studies in animals, and/or computational modeling studies can also provide essential information on the safety and effectiveness of a device (including its principles of operation, as well as potential failure or malfunction modes). That information can inform the clinical trial design and extent of premarket clinical evidence generation, as well as the extent of postmarket data that may be required.

DISADVANTAGES

1. Lost Innovation

Link: Passing AFFs plan adds to the approval process

Impact: U.S. Patients last in the world to receive medical innovations

Paul Citron, 2011 (Paul Citron is a founding member of the American Institute for Medical and Biological Engineering, retired from Medtronic, Inc., in 2003 after a 32-year career. Issues in Science and Technology is a quarterly journal published by the National Academy of Sciences and Arizona State University. The journal is a forum for discussion of public policy related to science and technology.) Issues in Science & Technology Vol. XXVII, No. 3, Spring 2011 "Medical Devices: Lost in Regulation" Spring 2011. https://issues.org/p_citron/ (accessed 16 May 2025)

In the 1950s and 1960s, technological innovations such as the cardiac pacemaker and prosthetic heart valve meant that thousands of suffering Americans had access to treatment options where none had existed before. And because so many breakthrough devices were developed in the United States, the nation's citizens usually had timely access to the latest technological advances. In addition, U.S. physicians were at the forefront of new and improved treatments because they were working alongside industry in the highly dynamic innovation process. In fact, they rose to worldwide preeminence because of their pioneering work on a progression of breakthrough medical therapies. But that was then. Although the United States is still home to numerous medical device companies, these companies no longer bring cutting-edge innovations to U.S. patients first. And U.S. clinical researchers now often find themselves merely validating the pioneering work that is increasingly being done in Europe and elsewhere in the world. Worse still, seriously ill patients in the United States are now among the last in the world to receive medical innovations that have secured regulatory approval and clinical acceptance elsewhere in the developed world. What's behind this erosion of leadership and late access to innovations? Simply stated, an overreaching, overly burdensome, and sometimes irrelevant Food and Drug Administration (FDA) regulatory process for the most sophisticated new medical devices.

2. Harms Patients

Link: Approval delays harm U.S. patients

Paul Citron, 2011 (Paul Citron is a founding member of the American Institute for Medical and Biological Engineering, retired from Medtronic, Inc., in 2003 after a 32-year career. Issues in Science and Technology is a quarterly journal published by the National Academy of Sciences and Arizona State University. The journal is a forum for discussion of public policy related to science and technology.) Issues in Science & Technology Vol. XXVII, No. 3, Spring 2011 "Medical Devices: Lost in Regulation" Spring 2011. https://issues.org/p_citron/ (accessed 16 May 2025)

Delays in the approval of effective devices do result in harm to patients who need them. If we examine the date of approval for the identical device in Europe and the United States, we see that most devices are approved much later in the United States. Three examples illustrate this point. Deep brain stimulation for ineffectively managed symptoms of tremors and Parkinson's disease was approved for use in the United States 44 months after European approval. A novel left ventricular assist device that permitted patients with severe heart failure to receive critical circulatory support outside the hospital was approved 29 months later. A pacemaker-like device that resynchronized the contraction sequence of heart muscle for patients suffering from moderate to severe heart failure was approved 30 months after it became available for patients in Europe.

Impact: U.S. patients miss life-saving benefits

Paul Citron, 2011 (Paul Citron is a founding member of the American Institute for Medical and Biological Engineering, retired from Medtronic, Inc., in 2003 after a 32-year career. Issues in Science and Technology is a quarterly journal published by the National Academy of Sciences and Arizona State University. The journal is a forum for discussion of public policy related to science and technology.) Issues in Science & Technology Vol. XXVII, No. 3, Spring 2011 "Medical Devices: Lost in Regulation" Spring 2011. https://issues.org/p_citron/ (accessed 16 May 2025)

The example of a minimally invasive transcatheter heart valve for the treatment of inoperable aortic stenosis illustrates the implications of excessive delay on the well-being of ill patients. Patients suffering from severe aortic stenosis have an estimated 50% mortality within 2 years after symptom onset if they do not undergo open-heart surgery for valve repair or replacement. Quality of life is adversely affected because of shortness of breath, limited exercise capacity, chest pain, and fainting episodes. A definable subset of affected patients includes those who are too frail to undergo the rigors of open-heart corrective valve surgery. The transcatheter approach, whereby a new replacement valve is inserted via the vasculature, much the way in which coronary balloon angioplasty is done, offers a much less invasive and less traumatic therapeutic option for the frail patient. Even though the technology and procedure are still evolving, clinical results have been impressive, and thousands of patients have received it. In a recently published clinical study, one-year mortality has been reduced by 20 percentage points when compared to the mortality of patients in the standard medical care group. Quality-of-life measures also improved substantially. The transcatheter heart valve was approved in Europe in late 2007; it is still awaiting FDA approval. A transcatheter valve of different design was approved in Europe in March 2007 and has produced impressive results in high-risk patients. Over 12,000 patients in Europe and 40 other countries where approval has been granted have received this valve. It too is still not approved in the United States. In the case of a disease with a poor prognosis, years of delay do not serve the best interests of affected U.S. patients, especially if there is credible clinical evidence that a new intervention performs well.

3. Lost Democracy and Corruption

Link: Passing AFFs plan bypasses U.S. rulemaking process

Link: Rulemaking Process Promotes Transparency

Government Accountability Office, Accessed May 2025 (The U.S. Government Accountability Office (GAO) is an independent, nonpartisan government agency within the legislative branch that provides auditing, evaluative, and investigative services for the United States Congress. It is the supreme audit institution of the federal government of the United States) "Federal Rulemaking" No Publication Date. (accessed May 14th, 2025) https://www.gao.gov/federal-rulemaking

Congress and presidents have worked to enhance oversight of the federal rulemaking process to promote greater transparency and public participation, and to reduce regulatory burden. For example, recent administrations have directed agencies to identify rules that are obsolete or in need of revision. More recently, President Biden issued an Executive Order directing the Office of Management and Budget (OMB) to recommend ways to improve and modernize the regulatory review process. The process for creating federal regulations generally has three main phases: initiating rulemaking actions, developing proposed rules, and developing final rules. In practice, however, this process is often complex, requiring regulatory analysis, internal and interagency reviews, and opportunities for public comments. Transparency of the regulatory process is important—it helps the public better understand the rulemaking process and aids in congressional oversight.

Link: Transparency promotes Democracy, decreases corruption

Coalition for Integrity, Accessed May 2024 (Coalition for Integrity is a non-profit, non-partisan 501(c)(3) organization. We work in coalition with a wide range of individuals and organizations to combat corruption and promote integrity in the public and private sectors.) "U.S. Transparency and Accountability" No Publication Date. (accessed May 14th, 2025) https://www.coalitionforintegrity.org/what-we-do/transparency-and-accountability/

The Coalition for Integrity believes that transparency and accountability are essential characteristics of democratic governance at the federal, state, and local levels. Transparency serves two important purposes. First, it serves to open the government to those it serves. A transparent government allows people to participate in the democratic process and to keep informed of government budgets, spending, and projects. Second, transparency is a powerful weapon against corruption. When government processes are transparent, it is difficult for corruption to thrive.

Impact: Hurts the Poor, the Economy, Increases Violence

The World Bank, 2023 (With 189 member countries, staff from more than 170 countries, and offices in over 130 locations, the World Bank Group is a unique global partnership: five institutions working for sustainable solutions that reduce poverty and build shared prosperity in developing countries.) "Corruption is a Global Problem for Development. To Fight It, We All Have a Role to Play" 13 June, 2023. (accessed May 14th, 2025) https://www.worldbank.org/en/news/opinion/2023/06/13/corruption-is-a-global-problem-for-development-to-fight-it-we-all-have-a-role-to-play

Corruption harms the poor and vulnerable the most, increasing costs and reducing access to basic services, such as health, education, social programs, and even justice. It exacerbates inequality and reduces private sector investment to the detriment of markets, job opportunities, and economies. Corruption can also undermine a country's response to emergencies, leading to unnecessary suffering and, at worst, death. Over time, corruption can undermine the trust and confidence that citizens have for their leaders and institutions, creating social friction and in some contexts increasing the risk of fragility, conflict, and violence.