The Bioscan
AN INTERNATIONAL QUARTERLY JOURNAL OF LIFE SCIENCES
20(3): S.I (3), 1127-1136, 2025 www.thebioscan.com

A RETROSPECTIVE ANALYSIS OF US FDA BREAKTHROUGH DEVICES PROGRAM: SETTING A GLOBAL REGULATORY BENCHMARK

K. MOUNIKA[1], T. SUDHEER KUMAR[1*], R. KAMARAJ[1].

[1]Department of Pharmaceutical Regulatory Affairs, SRM College of Pharmacy, SRM Institute of Science and Technology, Kattankullathur campus, Chengalpattu Dt, Tamil Nadu- 603203.

Corresponding Author: Dr. T. Sudheer Kumar

*Corresponding Author E-mail: tirumals@srmist.edu.in

ORCID ID- 0009-0009-6043-8016

DOI: 10.63001/tbs.2025.v20.i03.S.I(3).pp1127-1136

KEYWORDS
Approval trends, Breakthrough devices program, Designation, Expedited approval, Global regulatory benchmark, Life threatening conditions, Regulatory innovation.
Received on:

04-08-2025

Accepted on:

06-09-2025

Published on:

03-10-2025

ABSTRACT

U.S. Food and Drug Administration (FDA) created the Breakthrough Device Program to fasten the speed of development and review of medical technology to meet terminal illness or conditions that are debilitating and irreversible. This initiative was created to ensure faster patient access to promising innovations by enabling ongoing, early-stage dialogue with the FDA and prioritizing the review of qualifying submissions. Unlike the conventional regulatory framework, which can be time-consuming and complex, the Breakthrough Devices Program focuses on identifying and resolving regulatory barriers promptly. Eligible devices may follow various approval routes such as premarket approval (PMA), 510(k) premarket notification and De Novo classification, depending up on their risk category and innovation level. This study analyses the program's performance between 2022 and 2024, using publicly available FDA data, including device classifications and approval outcomes. Only devices that obtained marketing authorization during the study window were included in the final analysis. The findings reflect the program's success in enhancing timely access to medical innovation while maintaining safety and efficacy. Furthermore, the program is setting a precedent globally, serving as a model for other regulatory bodies aiming to balance speed and rigor in healthcare innovation.

INTRODUCTION

Bringing revolutionary medical devices onto the market involves a long complex process including wide-ranging testing and regulatory reviews with lengthy evaluations [1]. This schedule may present significant issues particularly when immediate entry is a key to devices diagnosing or curing disease which is life threatening or a permanently debilitating one. The Breakthrough Device Program was started to deal with this problem [2]. It was tailored only to the Food and Drug Administration (FDA) of Center for the Devices and Radiological Health i.e (CDRH) [3]. The Breakthrough Device Program accelerates, process of developing and reviewing devices that meet the healthcare needs of the seriously ill patients effectively as compared to the case with the standard regulatory path that is slow and cumbersome [4]. FDA provides pre-market as well as frequent interactions to the builders of the breakthrough-labeled machines. Such interactions do enable an extra rapid awareness as well as possibly provide a solution of regulation issues [5]. The FDA has given priority to marketing reports on such devices, that include premarketing approval denoted as (PMA), premarket notification as [510k] and the De Novo classification requests, amongst others. Review streamlining reduces delays that are in the program, and also innovations for life-saving gain access for patients at a more accelerated rate [6].

MEDICAL DEVICE:

A medical device refers to an instrument, tool, machine or implant that serves diagnostic, preventive, monitoring, treatment, or relief of disease and medical condition. They unlike pharmaceutical products are not meant to achieve their primary purpose by chemical or metabolic action but by physical or mechanical action. The technologies involve such simple machines as thermometers and syringes, to complicated ones that include pacemakers, surgical robots, and imaging tools. They are crucial in the contemporary health care as they lead to an increased level of accuracy, patient outcomes, and aid in clinical decision making [7]. Medical devices are regulated to different degrees and need varied levels of attention according to the type of devices and dangers of using them in providing general safety and principles of effectiveness. Medical devices are increasingly becoming important in the global setting as healthcare systems work towards achieving better quality, efficiency, and patient-centred practice [11].

US FDA BREAKTHROUGH DEVICE PROGRAM:

Breakthrough Device Program is an optional program which is considered to cover part of medical devices use of devices causing treatment or diagnosis on life-threatening diseases/disorders or permanently debilitating ones that are more efficient breakthrough devices program is optional [8]. The Breakthrough Device Program will speed up the process of reviewing and clearing of medical equipment to allow quick access to FDA approved/approvable medical devices by both patients and healthcare providers by providing development, evaluation and review approval of the premarket approval, 510(k) clearance or notification and de novo marketing of medical devices [6]. To be approved for marketing, the breakthrough device should meet FDA's high bars on the device or instrument performance and safety [5]. Our dedication to innovate in devising and health in the population protection is shown in the breakthrough devices program [9]. With regards to medical devices, the breakthrough device program is a substitute of the priority review and expedited Access pathway. To the FDA, device which fall under Expedited Access Pathway fall under Breakthrough Device Program [10]. The Breakthrough Device Program gives the manufacturers a chance of collaborating with FDA specialists and resolve emerging issues through a range of program options efficiently that appeared during the premarket review. As a result of this connection, producers will be able to establish points of accord very fast and access FDA comments. Also, the manufacturers could be assured that their filings will be considered on a priority basis [11].

BREAKTHROUGH DEVICE CRITERIA:

Premarket Approval applications, premarket notification [510k] or De Novo Designation request can be labeled as Breakthrough Device as long as the device coincides with either of the following one as shown in the Table. 1.

Primary Criterion:

- The device will aim at providing superior treatment or diagnosis of a debilitating or recurring physically incapacitating disease.
- **Additional Qualification** – Must Meet at Least One of the Following:

Qualification Area	Description	Guidance Reference
Innovative Technology	The product represents a novel or breakthrough technological approach	III.B.2.a
Lack of Alternatives	No Products that are approved currently or cleared products exist that serve the same function.	III.B.2.b
Superior Performance	Demonstrates significant improvement compared to existing alternatives.	III.B.2.c
patient-Centric Benefit	Its availability would provide meaningful benefits for patient care	III.B.2.d

Table. 1. Breakthrough Device criteria

The Breakthrough Devices Program aids patients faster via expediting revolutionary medical devices' development as well as review for treatments of life-saving or debilitating disease. It speaks to the demand for prompt device access. These devices effectively treat or diagnose serious conditions since current options lack effectiveness or sufficiency [11].

GUIDANCE DOCUMENTS:

- Guidance to the industry and food and drug administration staff
- https://www.fda.gov/regulatoryinformation/searchfdaguidance-documents/breakthrough-devices-program
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program [11].

APPROVAL PROCESS:

The Breakthrough Device Program that is provided on the U.S. FDA territory is aimed at the faster development and authorization of evaluation of certain medical devices in case the latter need to be more effective according to the results of treatment or diagnosis of terminal or incurably-disabling conditions or diseases [8]. Sponsor wishing to seek Breakthrough Device designation is required to submit a separate standalone Submission Request for Designation of Breakthrough Device (Q-Submission (Q-Sub)). This submission should contain the request of designation and it is advisable to file any other simultaneous fee payment request of feedback after the FDA has made an assessment of designation, as this can alter the type of feedback that is given [12]. The submission process for a Q-Sub is detailed in FDA guidance document that contains the Feedback, requests, and meetings of medical device submissions: The Q-Submission Program. It is possible to submit the Q-Submission electronically on the Center for devices and radiological health (CDRH) customer collaboration portal [11].

In some cases, the FDA may identify a device as a potential candidate in the Breakthrough Device Program and can encourage the sponsor to apply [13]. The designation request is supposed to provide extensive information to include description of the device, prediction of intended use, any history of regulations regarding the device, how the device has been found to fit the statutory requirements of a Breakthrough Device thereby making the request, and which type of marketing submission is intended to be filed by the sponsor (e.g., 510(k), PMA, De Novo). Extensive instructions on what to write in the request can be found on final guidance document [11].

Upon receiving the designation request, the FDA aims to request any necessary additional information within 30 days. The agency shall make a formal decision available within 60 calendar days after having received the request concerning said designation, granting or denying [14]. Sponsors should also be accessible and prompt at this stage, since failure to meet the set deadlines of providing requisite information may lead to lack of the designation [15].

If the FDA grants the Breakthrough Device designation, the sponsor becomes eligible for several types of prioritized and interactive communication with the FDA. These consist of sprint discussions to address any specific problem quick, requests on review of data development plans, and requests of clinical protocol agreements. These interactions are meant to help streamline the development and premarket review process [5]. Moreover, the FDA will give priority review status to all further regulatory submissions involving the designated device (such as additional Q-submissions, Investigational device exemption (IDE)- applications and the marketing applications [16].

When a particular device does not qualify to participate in the Breakthrough Device Program since it is not being aimed at treatment and diagnosis of a life-threatening condition or a disease, then sponsors could decide to apply to the Safer Technologies Program (STeP) where it is possible to receive the designation in cases where the device has a positive impact on safety, even though it is not eligible to be a Breakthrough device [17].

The FDA does not publicly address a device receiving Breakthrough Device designation until a marketing authorization has been hired in general. Once a device with Breakthrough designation has been authorized for marketing, the FDA may add it to a publicly available list of such devices. This confidentiality is maintained to protect proprietary information unless the sponsor voluntarily chooses to make the designation status public [5]. The approval process of breakthrough device program is shown in fig.1.

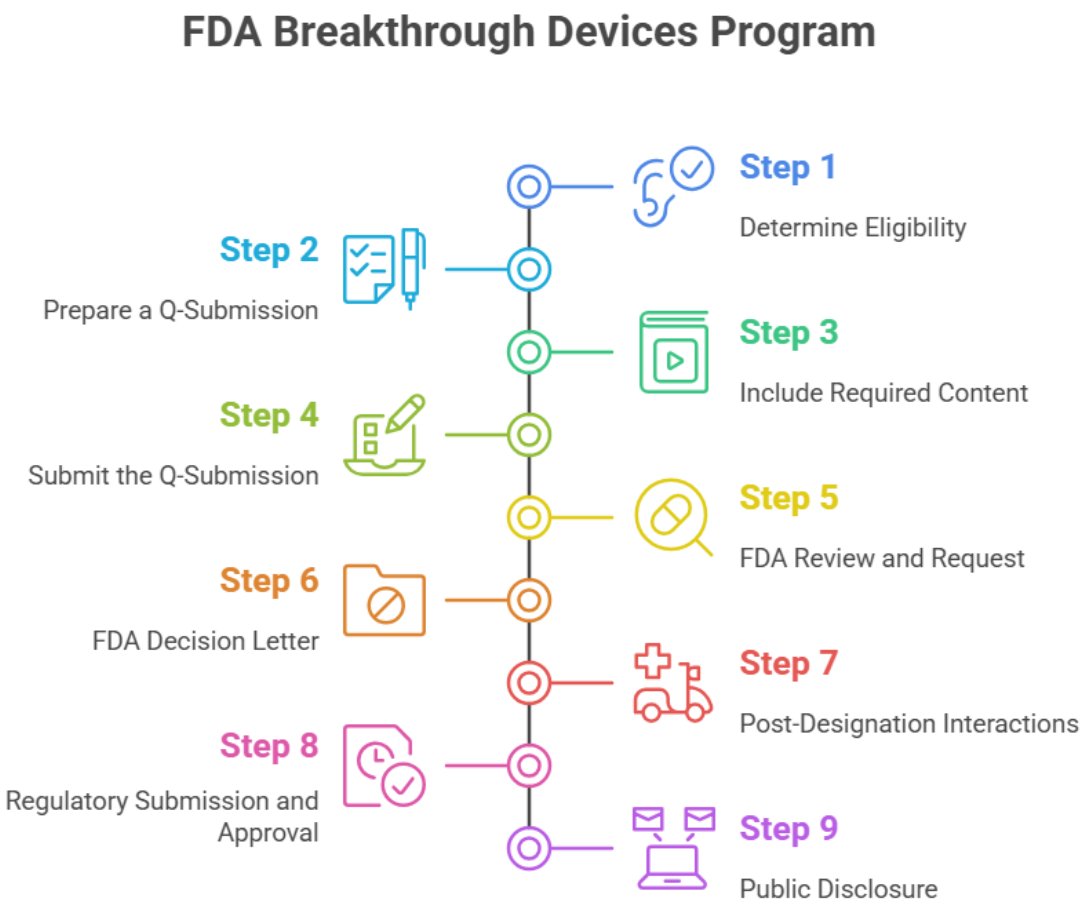


Fig. 1. Stepwise Approval Process: FDA Breakthrough Devices Program

STEPWISE APPROVAL PROCESS: FDA BREAKTHROUGH DEVICES PROGRAM

Step 1: Determine Eligibility:

Validate your device that is being designed in treating or diagnosing a life- threatening debilitating disease or illness in the human beings. Perform due diligence that your device fits the definition of a Breakthrough device, i.e.: a novel technology, in which no other approved/cleared competitors are available, and where there is considerable advantage over the existing competitors, and unmet medical need or condition [18].

Step 2: Prepare a Q-Submission for Designation:

Prepare a "Designation Request for the breakthrough device" as a standalone Q-Submission (Q-Sub). Do not include other feedback requests in the same submission. Consider delaying other pending Q-Sub feedback requests until after the FDA's designation decision [11].

Step 3: Include Required Content in the Designation Request:

Your request should include : Device Description – Technical details, mechanism of action, and key features, Proposed Indication for Use – What condition the device treats/diagnoses and the intended patient population, a regulatory history and any prior communications or submissions for FDA, Justification for the Breakthrough Criteria- Evidence and rationale showing how the device meets one or more of the statutory criteria, Planned Marketing Submission Type – e.g., 510k, PMA, DeNovo, etc [19].

Step 4: Submit the Q-Submission:

Submit your Q-Sub electronically through the CDRH Customer Collaboration Portal [11].

Step 5: FDA Review and Request for Information:

FDA may in the first 30 days, request more data to assist in the justification of the designation and also conducts short interactions in order to clarify. Be responsive and timely in providing additional information to avoid delays or denial [15].

Step 6: FDA Decision Letter:

Within 60 calendar days, the FDA will send a designation decision letter. Grant Letter: If criteria are met and Denial Letter: If criteria are not met or information is insufficient [20].

Step 7: Post-Designation Interactions (if granted):

Once granted designation, sponsors gain access to enhanced FDA interaction that includes sprint discussions – Short, focused meetings to address specific issues quickly, Data development plan meetings – Early alignment on preclinical and clinical data expectations and Clinical protocol agreement meetings – Formal FDA agreement on clinical protocols. Your future submissions for the device (e.g., IDE, marketing applications) will receive priority review [6].

Step 8: Regulatory Submission and Approval:

Proceed with your planned regulatory submission (e.g., PMA, De Novo). Leverage prioritized review and FDA feedback to streamline the path to market [21].

Step 9: Public Disclosure (After Marketing Authorization):

FDA does not disclose Breakthrough status publicly before marketing authorization. After authorization, FDA may add the device to its public list of marketed Breakthrough Devices [5].

Alternative Pathway (if not eligible):

In a case when your device does not qualify to become Breakthrough designation consider applying under the Safer Technologies Program (STeP), designed for devices that enhance safety but are not intended for life threatening or severely debilitating symptoms [17].

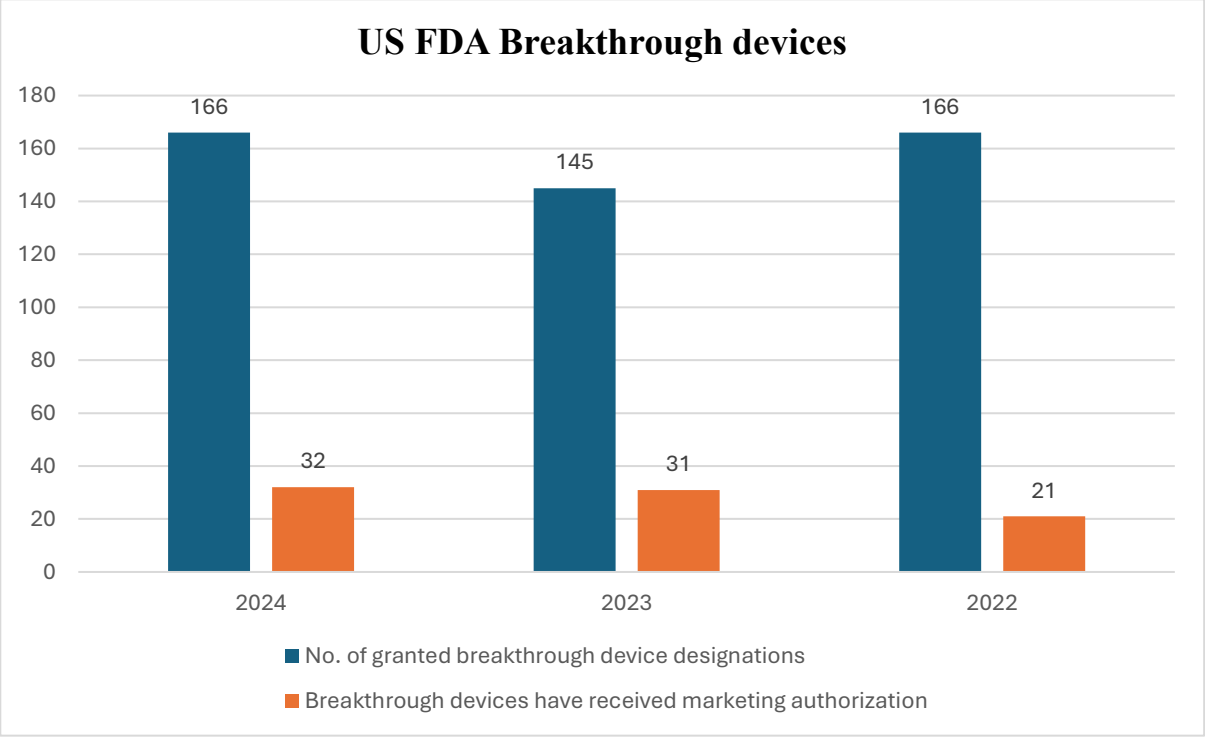
TIMELINE:

Within 30 days of getting your request, FDA will ask any other information that would be required to assist in the decision of whether the device should be designated a Breakthrough Device. In less than 60 days of calendar forwarding of your request to FDA receives your request, you will have an opportunity to obtain a letter notifying of the FDA decision regarding awards or denial of the Breakthrough Device designation [11].

METHODOLOGY:

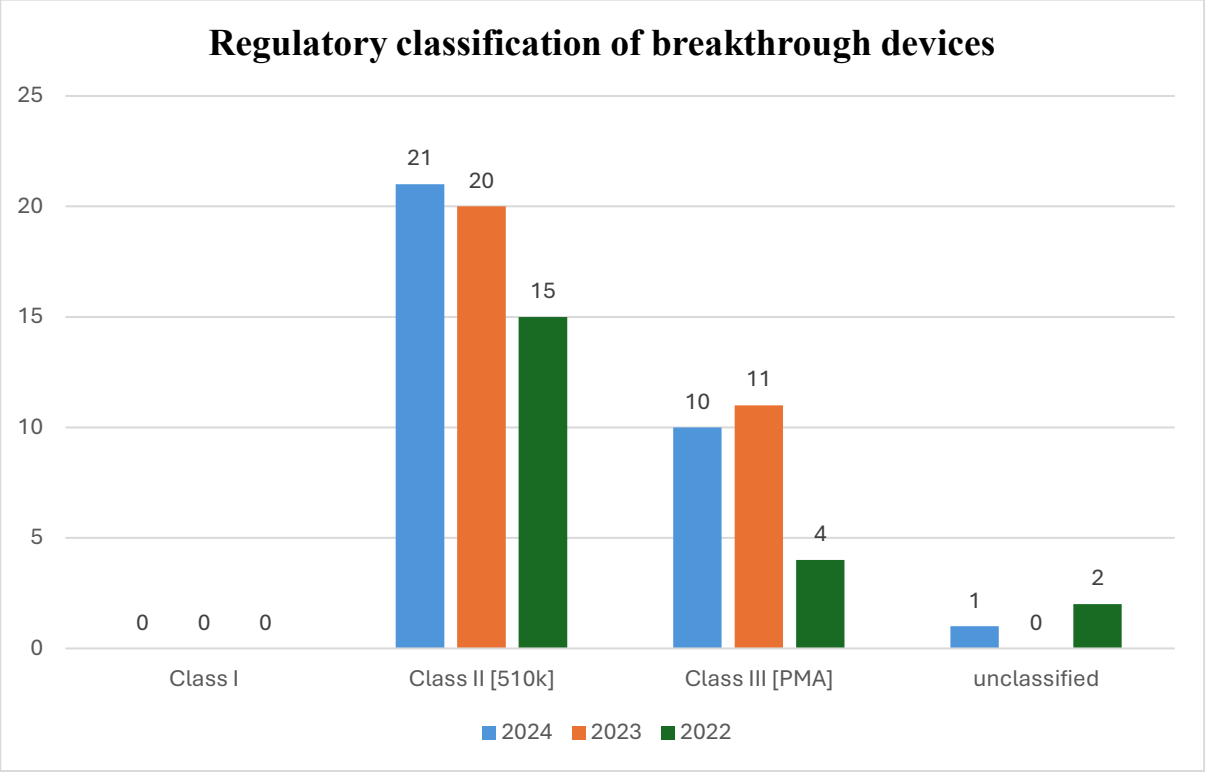
This study was conducted to evaluate the breakthrough device program for medical devices implemented by US FDA. The research focuses on identifying current trends, approval patterns, and regulatory outcomes associated with breakthrough – designated devices between years (2022- 2024). Data was collected from publicly available FDA databases, including FDA breakthrough devices designation approval list, premarket approval (PMA) and 510k databases. The cumulative figure of the breakthrough devices granted designation and those receiving marketing authorization were tabulated for each year. Devices granted breakthrough status during the study period were identified, and their marketing authorization status was verified by cross-referencing with the PMA and 510(k) databases. Only those devices that received marketing authorization within the period were included in the approval outcome analysis. The authorized breakthrough devices were categorized into the regulatory risk classes: the specifications provided by the FDA on breaking down risk-based categorization of medical devices that include Classes I (low risk), II (moderate risk usually as 510(k)), Class III (high risk that requires PMA), and unclassified. Devices were then grouped by year of approval (2022, 2023, and 2024), and detailed information on device name, regulatory classification, and approval pathway was recorded. Additionally, devices were categorized based on their respective medical specialties to evaluate approval trends across different clinical areas. This approach enabled a comprehensive assessment of breakthrough device designation patterns, regulatory pathways, and specialty-specific approvals over the three-year timeframe.

RESULTS AND DISCUSSION:



Graph. 1. Number of Breakthrough Device Designations and marketing authorization granted by USFDA

The Graph. 1, shows the number of the Breakthrough Device Designation issued and distance that the breakthrough devices obtained a marketing permit between years 2022 and 2024. In **2022**, **166** devices were granted breakthrough designation, and **21** of those received marketing authorization. In **2023**, the number of designations slightly dropped to **145**, while the number of authorized devices increased to **31**. In **2024**, the number of designations returned to **166**, matching 2022's count, with **32** devices obtaining marketing authorization — the highest among the three years. Overall, while the number of designations remained relatively high across all three years, the number of devices achieving marketing authorization has **steadily increased**, indicating possible improvements in regulatory pathways or product readiness.



Graph. 2. Regulatory classification of breakthrough devices

The Graph. 2, shows regulatory classification of the breakthrough devices receiving marketing authorization between 2022 and 2024: Class I, II (510k) and III (PMA) and Unclassified. In the three years, no marketing authorizations were available particularly on class I devices. The Class II (510(k)) devices continuously occupied the biggest division, as in 2022, 2023, and 2024, it was counted as 15, 20 and 21, respectively. The class III (PMA) devices normally linked to the highest risk and the most thorough review were also on the increase in 2023 (by 11) and 2024 (by a bit, 10). The unclassified hardware was negligible, and 2 are currently existing in 2022, 0 in 2023, and 1 in 2024. This information indicates a rising tendency in the count of class II and class III breakthrough device's attaining authorization, which indicates continued creativity in extra-complex and moderate-to-high-risk medical technologies.

The Table 2 shows the list of breakthrough devices that received marketing authorisation in the year 2024.

Year	Device name	Classification	Approval pathway
2024	Percutaneous catheter for cutting heart valve leaflets concomitant to transcatheter valve procedures	II	510K
	Minima stent system	III	PMA
	Altius Direct Electrical Nerve stimulation System	III	PMA
	Sacroiliac Joint fixation	II	510K
	Dressing, Wound, Drug. Burn Contact Dressing	Unclassified	510K
	Automated Antimicrobial Susceptibility Test System	II	510K
	Icotec Anterior cervical Plate system	II	510K
	ophthalmic optical coherence Tomography Imaging Device	II	510K
	Colorectal Neoplasia, RNA Markers & Hemoglobin Detection	III	PMA
	Automated Antimicrobial susceptibility test system	II	510K
	Scaffold, Infrapopliteal, Absorbable	III	PMA
	Fluorescence Imaging tor Breast cancer Detection	III	PMA
	Opportunistic Evaluation of low Bone Mineral Density Radiology software	II	510K
	pulmonary hypertension ML -Based Notification software	II	510K
	Invertebral fusion Device with Bone Graft, Lumbar	II	510K
	Spinal Vertebral Body Replacement Device	II	510K
	Tricuspid Valve Repair device, percutaneously delivered	III	PMA
	Test, opiates, OTC Insta strip fentanyl Rapid test (urine)	II	510K
	Reduced Ejection Fraction ML Based Software	II	510K
	Brain trauma Assesment test	II	510K
	Filler, Bone Void and Ca+Compound Containing single aminoglycoside	II	510K

	Ankle fusion cage	II	510K
	Drug eluting percutaneous Transluminal coronary Angioplasty catheter	III	PMA
	Thoracolumbo sacral pedicle Screw System	II	510K
	Blood culture processor for Antimicrobial Susceptibilty testing	II	510K
	Marker, Radiographic, Implantable	II	510K
	Percutaneously Delivered Prostheses & tricuspid Valves	III	PMA
	Percutaneous Cardia Ablation Catheter	III	PMA
	Intra oral Cooling Device	II	510K
	Software aided Adjunctive Diagnostic Device	II	510K
	Wearable vibration Device	II	510K
	Endovascular System for treatment of thoraco abdominal & Pararenal Aortic lesions	III	PMA

Table. 2. List of breakthrough devices that received marketing authorisation in the year 2024

Table 3 shows the list of breakthrough devices that received marketing authorisation in the year 2023.

Year	Device name	Classification	Approval pathway
2023	Endoscopic Ultrasound System	II	510K
	Avert D Buccal Sample collection kit	III	PMA
	Percutaneous Cardia Ablation Catheter	III	PMA
	Acute kidney Injury test system	II	510K
	Ablation Catheter, Renal Denervation (SPYRAL)	III	PMA
	Ablation Catheter, Renal Denervation (ultrasound)	III	PMA
	Aspiration Catheter, thrombus retriever	II	510K
	Edison system	II	510K
	Low Ejection Fraction AI-ECG	II	510K
	Extra Vascular Support VasQ	II	510K
	Limflow system	III	PMA
	Biopsy Needle	II	510K
	Annalise enterprise CTB triage- OH	II	510K
	Unit, Cryosurgical accessories	II	510K
	prognostic test (for assessing kidney)	II	510K
	Leadless pacemaker	III	PMA
	Mechanical & Enzymatic Autologous skin processor	III	PMA
	DETOUR system	III	PMA
	Automatic Event Detection Software	II	510K
	prognostic test for preeclampsia	II	510K
	Computerized Behavioral therapy Device	II	510K
	system, Endovascular graft, Aortic Aneursym treatment	III	PMA
	Stimulator, Nerve, for restless leg syndrome	II	510K
	Medial knee Implanted shock Absorber	II	510K
	Monitor for opiod induced impairment of oxygenation	II	510K
	Absorbable metallic bone fixation fastener	II	510K
	powered Exoskeleton	II	510K
	Brain trauma Assessment test	II	510K
	Fludeoxy glucose F18-guided radiation Therapy system	II	510K
	Prosthesis, posterior spinal elements	III	PMA
	Mechanical & enzymatic Autologous skin processor for cell suspension	III	PMA

Table. 3. List of breakthrough devices that received marketing authorisation in the year 2023

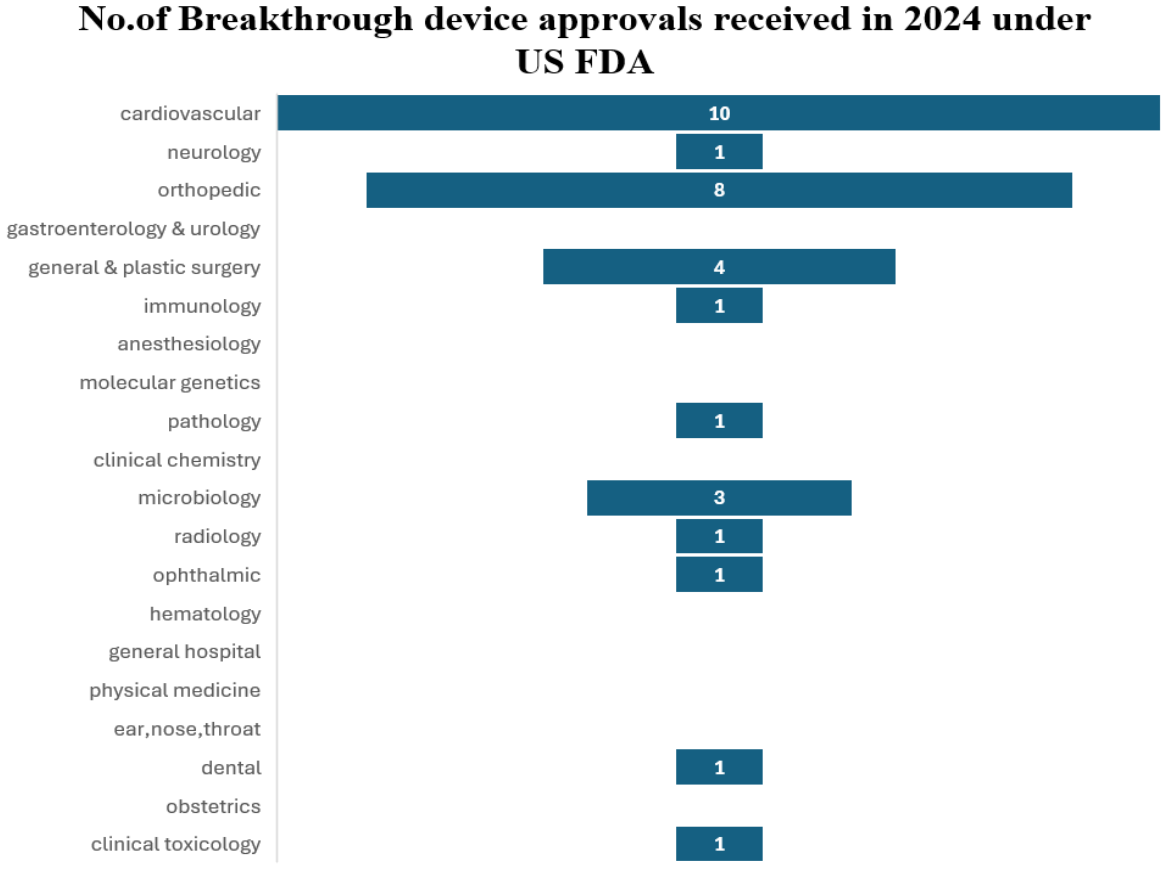
Table 4 shows the list of breakthrough devices that received marketing authorisation in the year 2022.

Year	Device name	Classification	Approval pathway
2022	Sacroiliac Joint Fixation	II	510K
	Alzheimer's Disease pathology. Assessment test	II	510K
	Adjunctive Heart Failure Status Indicator	II	510K
	External Upper limb tremor Stimulator	II	510K

	Intervertebral Fusion Device with integrated fixation Lumbar	II	510K
	Dressing, wound, Drug	unclassified	510K
	Intra oral cooling device	II	510K
	oropharyngeal Electrical stimulator	II	510K
	Transcranial magnetic stimulator	II	510K
	Perineometer	II	510K
	Pediatric Autism spectrum Disorder diagnosis AID	II	510K
	Sacroiliac Joint fixation	II	510K
	Transcutaneous Electrical nerve Stimulator to treat Fibromyalgia symptoms	II	510K
	Filler, Bone Void and Ca+Compound Containing single aminoglycoside	II	510K
	System, Endovascular graft, Aortic aneurysm treatment	III	PMA
	Alzheimer's disease pathology Assessment test	II	510K
	organ care heart system	III	PMA
	Apparatus, Vestibular, Analysis	Unclassified	510K
	Hybrid stent graft, thoracic aortic lesion treatment	III	PMA
	Implant, Resorbable, for articular osteochondral repair	III	PMA
	Omnipod 5 automated insulin delivery system	II	510K

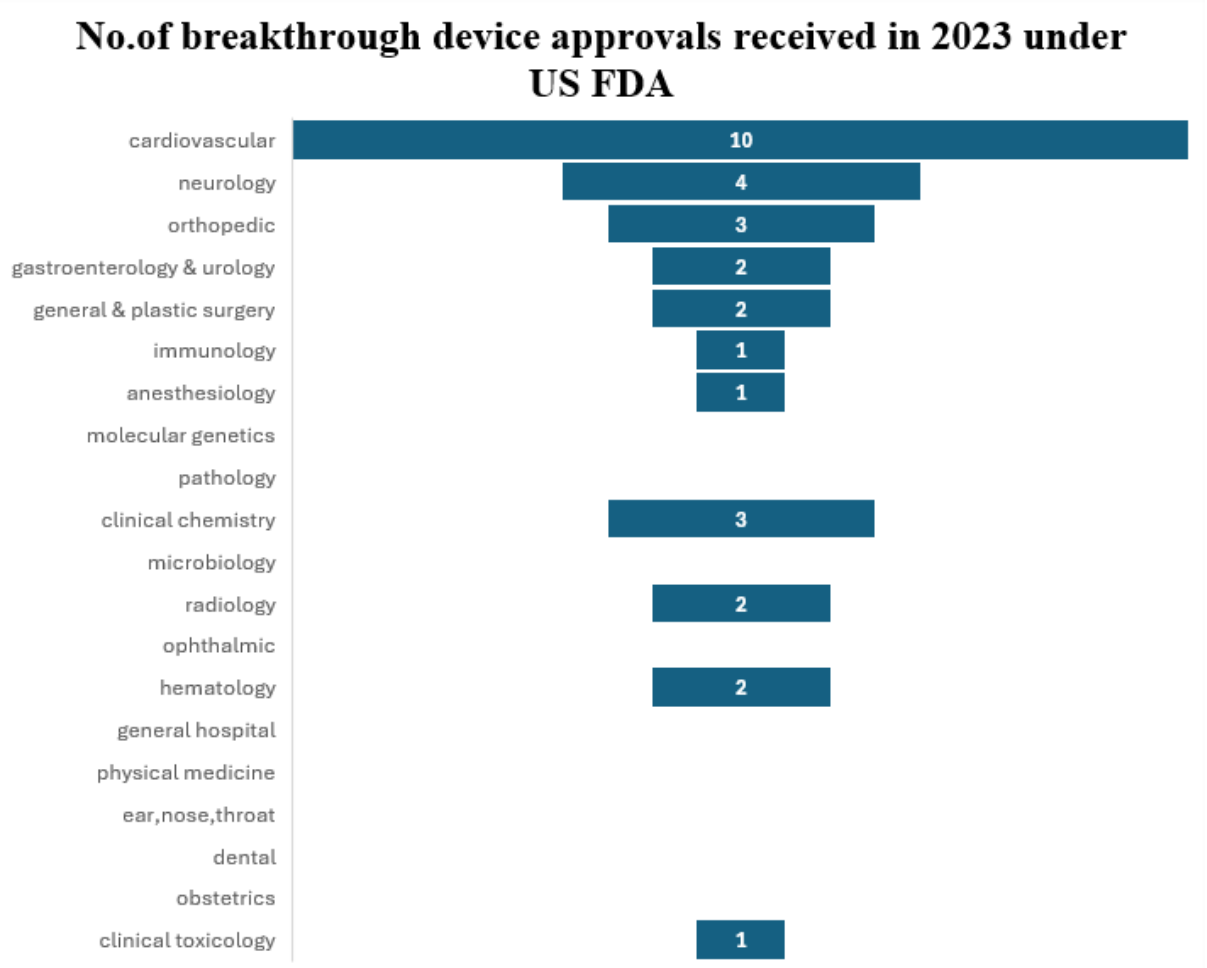
Table. 4. List of breakthrough devices that received marketing authorisation in the year 2022

Between **2022** and **2024,** a total of **84** breakthrough medical devices received FDA marketing authorization—**21** in **2022**, **31** in **2023**, and **32** in **2024**—showing a steady annual increase. Most of these devices were in Class II as such usually means medium risk and are usually cleared by 510(k) method. Class III devices, which represent higher-risk technologies requiring more rigorous evaluation through the PMA (Premarket Approval) process, also saw a rise—from 4 in 2022 to 11 in 2023, and slightly decreasing to 10 in 2024. A small number of unclassified devices appeared in 2022 and 2024. No Class I devices were approved during this period. The authorized devices spanned a wide range of medical areas, including cardiology, neurology, orthopedics, diagnostics, and digital health. Notably, there was a growing trend in application of machine learning-related software and AI, as well as the development of minimally invasive and implantable technologies.



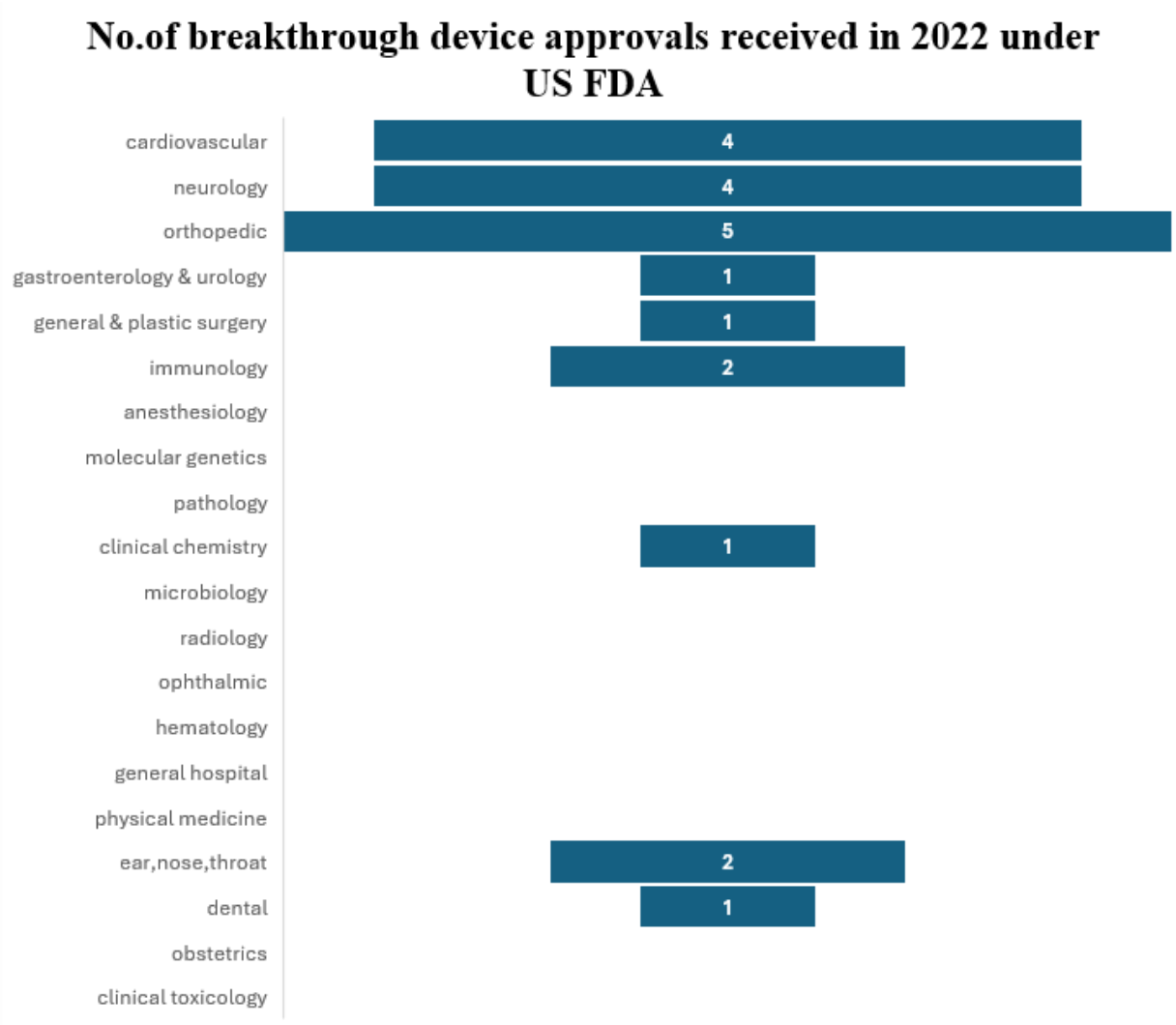
Graph. 3. No. of Breakthrough device approvals received in 2024 under US FDA for medical speciality.

In 2024, breakthrough device approvals were highest in cardiovascular (10) and orthopedic (8), reflecting strong innovation in heart and musculoskeletal care. General and plastic surgery had 4 approvals, and microbiology had 3, indicating notable progress in surgical and infectious disease technologies. Neurology, immunology, pathology, radiology, ophthalmic, dental, and clinical toxicology each had 1 approval, showing limited but meaningful advancements. No approvals were recorded in gastroenterology & urology, anesthesiology, molecular genetics, clinical chemistry, hematology, general hospital, physical medicine, ENT, or obstetrics, indicating minimal activity in those areas as depicted in Graph. 3.



Graph. 4. No. of Breakthrough device approvals received in 2023 under US FDA for medical speciality.

In 2023, cardiovascular devices led breakthrough approvals with 10, followed by neurology (4) and orthopedic (3), reflecting continued focus on heart, brain, and musculoskeletal innovations. Moderate activity was seen in clinical chemistry (3), gastroenterology & urology (2), general & plastic surgery (2), radiology (2), and hematology (2), indicating a broader spread of technological advancements. Immunology, anesthesiology, and clinical toxicology each had 1 approval, showing limited innovation. There were no approvals, shown in molecular genetics, pathology, microbiology, ophthalmology, general hospital, physical medicine, ear, nose, throat, [ENT], dentistry, or maternity which indicates little or no breakthrough activity in these areas as illustrated in the Graph. 4.



Graph. 5. No. of Breakthrough device approvals received in 2022 under US FDA for medical speciality.

In 2022, the highest number of breakthrough device approvals were in orthopedic (5), cardiovascular (4), and neurology (4), indicating key innovation in musculoskeletal, heart, and brain-related technologies. Moderate activity was seen in immunology (2) and ENT (2), while gastroenterology & urology, general & plastic surgery, clinical chemistry, and dental each had 1 approval. No approvals were recorded in anesthesiology, molecular genetics, pathology, Microbiology, radiology, ophthalmic, and hematology in addition to general hospital, physical medicine or obstetrics, or clinical toxicology, innovation in these areas for the year as shown in Graph. 5.

CONCLUSION

The Breakthrough Devices Program developed by FDA has become one of the most important regulatory efforts to accelerate the process of developing and approving new technological solutions in medicine that are designed to be applied in the area of serious, fatal or life-endangering diseases. Analysis of the breakthrough device data between 2022 and 2024 reveals a steady increase in both the number of devices receiving designation and those ultimately achieving marketing authorization. Most approvals occurred through the 510(k) rather than PMA pathways, with a predominant representation in Class II and Class III risk categories, respectively. This suggests that while the program facilitates accelerated access, it maintains regulatory rigor, especially for higher-risk devices. Notably, the diversity of medical specialties represented among approved devices underscores the broad impact of the program across clinical disciplines—from cardiology, orthopedic and neurology to dental and clinical toxicology. Beyond its national impact, the FDA's has developed a Breakthrough Devices Program that is increasingly regarded as a global benchmark for the regulatory innovation. Several international regulatory agencies have looked to the program as a model for designing their own expedited pathways, recognizing its balance of innovation support and patient safety assurance. This reinforces the FDA's leadership role in shaping global standards for medical device regulation. Overall, the findings reflect the program's effectiveness in streamlining regulatory pathways without compromising safety, thereby fostering timely patient access to transformative healthcare technologies. Continued refinement and transparency of the Breakthrough Devices Program will be essential to support innovation while ensuring robust oversight in an evolving medical landscape.

ACKNOWLEDGEMENT

The authors would like to express their sincere gratitude to the Department of Pharmaceutical Regulatory Affairs, SRM College of Pharmacy, SRM Institute of Science and Technology, Kattankulathur campus, for providing the necessary support and infrastructure to carry out this study. Special thanks to the faculty members and technical staff for their guidance and valuable suggestions throughout the course of the research

Conflict of Interest

The authors declare no conflict of interest related to the content or publication of this manuscript.

Funding Source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics Statement

This retrospective research does not involve human participants, animal subjects, or any materials that requires ethical approval.

Informed Consent Statement

This research did not involve human participants, and therefore, informed consent was not required.

Clinical Trial Statement
This research does not involve any clinical trials.

REFERENCES

- Khinvasara T, Ness S, Shankar A. Leveraging AI for Enhanced Quality Assurance in Medical Device Manufacturing. Asian Journal of Research in Computer Science. 2024 Apr 8;17(6):13–35.
- Srivastava Y, Virk S, Hazra S, Ganguli S. An overview of the various medical devices for diagnosis, monitoring, and treatment of diseases. In: Electronic Devices, Circuits, and Systems for Biomedical Applications. Elsevier; 2021. p. 379–403.
- Pietzsch JB, Aquino LM, Yock PG, Paté-Cornell ME, Linehan JH. Review of U.S. Medical Device Regulation. J Med Device. 2007 Dec 1;1(4):283–92.
- Rosenblatt M, Boutin MM, Nussbaum SR. Innovation in Medicine and Device Development, Regulatory Review, and Use of Clinical Advances. JAMA. 2016 Oct 25;316(16):1671.
- James L. Johnston SSDJSR& VKR. Early experience with the FDA's Breakthrough Devices program .
- Gupte T, Nitave T, Gobburu J. Regulatory landscape of accelerated approval pathways for medical devices in the United States and the European Union. Front Med Technol. 2025 May 15;7.
- Jarow JP, Baxley JH. Medical devices: US medical device regulation. Urologic Oncology: Seminars and Original Investigations. 2015 Mar;33(3):128–32.
- Donnelley CA, Devlin VJ, Harris MB, Poggie RA, Sanders RW, Morshed S. Regulation of orthopaedic devices: Future implications for research and innovation. OTA Int. 2021 Apr;4(2S):e101.
- Woo JH, Kim EC, Kim SM. The current status of breakthrough devices designation in the United States and innovative medical devices designation in Korea for digital health software. Expert Rev Med Devices. 2022 Mar 4;19(3):213–28.
- Tarricone R, Banks H, Ciani O, Brouwer W, Drummond MF, Leidl R, et al. An accelerated access pathway for innovative high-risk medical devices under the new European Union Medical Devices and health technology assessment regulations? Analysis and recommendations. Expert Rev Med Devices. 2023 Apr 3;20(4):259–71.
- https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.
- Scott PD, Bajaj A, McMullen DP. Navigating the FDA regulatory landscape. Neuropsychopharmacology. 2024 Jan 18;49(1):18–22.
- Kwok M, Foster T, Steinberg M. Expedited Programs for Serious Conditions: An Update on Breakthrough Therapy Designation. Clin Ther. 2015 Sep;37(9):2104–20.
- Sawyers CL HDHSISSW. Developing standards for breakthrough therapy designation. Cancer Research. 2012 Nov. 2012 Nov;
- Chandra A, Kao J, Miller KL, Stern AD. Regulatory Incentives for Innovation: The FDA's Breakthrough Therapy Designation. Review of Economics and Statistics. 2024 Mar 18;1–46.
- Patel A. Introduction to Medical Device Regulation. In Navigating the FDA Regulatory Processes. 2025 Jan 31;69–87.
- Lottes AE, Cavanaugh KJ, Chan YYF, Devlin VJ, Goergen CJ, Jean R, et al. Navigating the Regulatory Pathway for Medical Devices—a Conversation with the FDA, Clinicians, Researchers, and Industry Experts. J Cardiovasc Transl Res. 2022 Oct 14;15(5):927–43.
- Darrow JJ, Avorn J, Kesselheim AS. FDA Regulation and Approval of Medical Devices: 1976-2020. JAMA. 2021 Aug 3;326(5):420.
- Frisch E, Clavier L, Belhamdi A, Vrana NE, Lavalle P, Frisch B, et al. Preclinical in vitro evaluation of implantable materials: conventional approaches, new models and future directions. Front Bioeng Biotechnol. 2023 Jul 27;11.
- Kepplinger EE. FDA's Expedited Approval Mechanisms for New Drug Products. Biotechnol Law Rep. 2015 Feb;34(1):15–37.
- Kearney SJ, Lowe A, Lennerz JK, Parwani A, Bui MM, Wack K, et al. Bridging the Gap: The Critical Role of Regulatory Affairs and Clinical Affairs in the Total Product Life Cycle of Pathology Imaging Devices and Software. Front Med (Lausanne). 2021 Nov 17;8.