Annual Report

2024 State of US MedTech Regulation

Strategic insights and guidance for MedTech executives, regulatory leaders, and funders to navigate the US regulatory landscape and path to market for innovative medical devices in 2024 and beyond.

Soumya Mahapatra, Dr. Dhriti Roy, Kwame Ulmer, Christian Johnson

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Essenvia

A Message from our Founder and CEO

As the CEO of Essenvia, I am proud to present our 2024 State of US MedTech Regulation Report.

This comprehensive industry analysis represents our unwavering commitment to thought leadership and our dedication to advancing the MedTech industry through rigorous research and strategic intelligence.

By meticulously capturing the dynamic regulatory landscape, our report offers MedTech CEOs, CxOs, Regulatory Affairs Vice Presidents and executives, and investors unparalleled insights into navigating the challenges and seizing the opportunities ahead in the second half of the decade. A special thank you to my co-authors and our collaborators for making this report possible.

This year, our findings underscore the pivotal shifts within the MedTech sector, highlighting the importance of digital transformation, the integration of Artificial Intelligence and machine learning, and the breakthroughs in medical device innovation. These insights are crucial for strategic decision-making, ensuring your organization stays at the forefront of technological and regulatory advancements.

We invite MedTech leaders to connect with our Essenvia leadership team. Together, we can explore how our expertise and next-generation solutions can support your ambitions to transform healthcare delivery, enhance patient outcomes, and accelerate time-to-market for groundbreaking medical technologies. Join us in shaping the future of MedTech.

Sincerely,

Soumya Mahapatra
Founder & CEO, Essenvia, Inc.

About Essenvia:

Founded in 2018, Essenvia is a US-headquartered tech company that provides innovative solutions for MedTech and Healthcare companies to expedite the time-to-market of impactful healthcare technologies and solutions. Essenvia's flagship product, the Essenvia Regulatory (RIM) Platform, offers MedTech companies a centralized hub to streamline and accelerate regulatory activities of medical products to ensure compliance and achieve business KPI's, including regulatory submissions, registrations, change management, product launches, and regulatory intelligence. Our mission is to guide MedTech companies toward regulatory excellence for the purpose of accelerating delivery of innovative medical solutions to patients and providers.

Learn more at www.essenvia.com

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A Special Thank You to our Collaborators:

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Introduction

In mid-year 2023, Essenvia's Regulatory Intelligence team identified a pivotal shift unfolding in the Medical Technology industry throughout 2023, particularly within the United States and under the purview of the Food and Drug Administration (FDA).

The industry, in a notable regulatory evolution, transitioned from a position of crisis and rapid response throughout the SARS-CoV-2 Pandemic, towards an initiative-taking recalibration and reinvestment phase focused on digital transformation and artificial intelligence, incentivization of innovation, and the movement towards integration of emerging technologies.

Recognizing the significance of this transformation and the need for a comprehensive analysis, Essenvia embarked on a mission to capture this dynamic moment in the form of a detailed annual report. The report, aptly titled the "State of US MedTech Regulation," serves as a unique "time capsule" meticulously crafted to dissect the evolving regulatory landscape. By enlisting the insights of the FDA database combined with industry experts and collaborating closely with stakeholders, the Essenvia team aimed to provide a holistic view of the regulatory shifts, challenges, and opportunities impacting the medical device sector in the United States in 2024.

The purpose of the report extends beyond mere documentation; it seeks to serve as a valuable resource for industry players, policymakers, and stakeholders intended to drive action. The annual report delves into the intricacies of ever-changing regulatory policies, procedures, and programming, offering a nuanced understanding of the forces shaping the industry's trajectory. Essenvia's commitment to accuracy and depth in its analysis ensures that the report becomes an indispensable guide for navigating the evolving landscape of medical device regulations.

Methodologically, the report draws its strength from a blend of data-driven insights leveraging the FDA website, FDA and company press releases, the FDA database and secondary data channels, expert opinions, and collaborative input from key stakeholders. By combining quantitative and qualitative approaches, Essenvia strives to present a comprehensive overview that not only captures the current state but also provides strategic foresight for industry participants. The "State of US MedTech Regulation" annual report by Essenvia is an authoritative piece on events in the year prior, and a forward-looking resource that not only reflects the industry's journey in 2023 but also guides executives, investors, and policymakers in years ahead.

Executive Guidance

Executive Insights

The United States MedTech Industry exceeded 2022 expectations in 2023 as a year of policy transition and recalibration beyond the COVID-19 pandemic. While the industry faced economic recovery and experienced challenges with recalls, layoffs, and company shutdowns, 2023 also embodied a period of digital transformation policies and programs complimented by a boost in energy, chatter, and race for artificial intelligence – with an exploding interest in use cases for Generative AI – as well as innovative, digital, and breakthrough medical devices and technologies.

This report sheds light on the key events, milestones, and insights about the state of the industry in 2023 and what it means for MedTech executives in 2024. Here is a summary of key insights and impacts:

2023 was a Record-Breaking year that reinforces the US as the go-to-market for MedTech Innovation. Multiple records and milestones were achieved for innovative medical devices in 2023. **First, the FDA approved more novel De Novo devices in 2023 (46) than any year in history**; the prior record was held in 2018 (44). This record reveals a possible Second Rising Wave of De Novos with the first wave in 2013-2018 observing a year-over-year increase peaking at 44 devices followed by a drop to 22 devices in 2019. Over the last five years since, De Novos climbed from 22 to 46 per year, exceeding the previous record by two devices. We call this rise the Second Rising Wave. Also, Class III Pre-Market Approvals (PMA) had a significant year, with 35 PMA originals (half implants, half non-implants) obtaining FDA approval. Further, Breakthrough Devices are on track in 2024 to break through the 1000 devices designated-to-date threshold since the program's inauguration, with 167 designations granted in 2023 for a total of 921 designations since the program's inception (including Expedited Pathway) and 95 devices authorized for market. Further, the Center for Medicare & Medicaid Services (CMS) announced the Transitional Coverage for Technologies (TCET) pathway to expedite coverage for certain breakthrough designated devices, starting with five devices per year, to streamline efforts between the FDA and CMS. Finally, a wave of new guidance for AIML, combined with continued growth in AI/ML-enabled devices obtaining clearance or approval, demonstrated an advancement for MedTech transformation.

Why it matters?

The unprecedented approval of novel De Novo and PMA devices in 2023, alongside breakthrough device designations on track to surpass 1,000, underscores a historic period of innovation and regulatory receptiveness in the U.S. MedTech sector. The introduction of the TCET pathway by CMS further streamlines market access for groundbreaking technologies. These developments, combined with regulatory advances in AI/ML, present pivotal opportunities for strategic expansion, more predictable regulatory navigation, and bold investment, offer honorable acknowledgement to the FDA for its commitment to advancing innovation even throughout a pandemic, and highlighting the U.S.'s dominant role as the leader in global MedTech innovation.

Total FDA medical device submission decisions grew in 2023 over prior year, with 3%, 109%, and 59% growth rates for 510(k) clearances, De Novo clearances, and Pre-Market Approval (PMA) respectively. Over 3,300 medical devices achieved 510(k) clearance in 2023, exceeding prior year by 105 clearances. De Novos also leaped with a 2X increase from 22 to 46 clearances in 2022 to 2023 respectively. PMA' s also grew year-over-year at 60% from 22 in 2022 to 35 pre-market approvals in 2023.

Pathway	Median Time from Submission to FDA Decision (Months)	Total #
510(k)	4.5	3,300
De Novo	10.5	46
PMA Original	14.3	35

Overall, De Novos and PMAs continue to require more rigorous reviews than Class II 510(k) devices, with Median time from Submission to FDA Decision for De Novos taking 2.5x longer than 510(k) and PMA's taking 3x longer than review for 510(k) clearances.

Why it matters?

The significant growth in FDA medical device approvals in 2023, especially in De Novo and PMA pathways, highlights the rapid innovation and expansion in the medical device sector following the COVID-19 Pandemic, promising enhanced healthcare solutions and technologies for patients.

MedTech Digital Transformation, Artificial Intelligence, and the Year of Generative AI:

2023 was a watershed moment for expansion of AI/ML-enabled devices and the integration of Generative AI in the MedTech industry, highlighted by their prominent role as Keynote topics at key conferences and the surge in over 700 AI/ML-enabled Medical Device entries into the US Market to date. The FDA introduced new guidelines for Predetermined Change Control Protocol and Good Machine Learning Practices to ensure the safety and efficacy of AI-enabled technologies. The strategic importance of investing in AI/ML was underscored, with a focus on enhancing diagnostic accuracy and patient outcomes, and well as operational efficiencies for manufacturers and health systems alike. Additionally, the sector faced the imperative of addressing cybersecurity and modernizing clinical practices through digital innovations, laying a foundation for continued growth and innovation into 2024.

Why it matters?

The integration of AI/ML in MedTech signifies a pivotal shift towards more precise diagnostics and operational efficiency, underscoring the necessity for companies to adapt to and invest in these technologies. The FDA's new guidelines for AI/ML devices ensure safety and efficacy, marking a clear pathway for innovation and regulatory compliance. Embracing these advancements is crucial for maintaining a competitive edge and addressing evolving

A Breakthrough Year for Breakthrough Devices:
Breakthrough Device Designations are on track to hit a historic milestone of exceeding 1,000 designations in 2024, with 921 designations granted by end of 2023. Further, CMS's TCET reimbursement proposal brings promise of industry-desired reimbursement coverage for emerging technologies that address significant unmet needs, albeit reimbursement only covers five devices today.

Why it matters?

This surge in Breakthrough Device Designations signals a ripe environment for innovation, with the potential for expedited development and market entry. The CMS's reimbursement proposal further incentivizes the pursuit of innovative technologies, offering a clearer path to commercial viability and enhanced patient access to novel treatments that meet critical health needs. However, reimbursement remains a promise and a barrier unless TCET expands the number of designated devices participating down the road beyond five devices.

80% of all 510(k) clearances, the bulk of US submissions, were represented by eight medical specialties and review panels, led by Orthopedic (610), Radiology (450), General and Plastic Surgery (409), and Cardiovascular (325).

Approximately 50% of De Novos were granted for Microbiology (6), mostly driven by COVID-19 era EUA's transitioning to regulated IVD devices, and the remaining being Gastroenterology and Urology (6), General Hospital (5), and Cardiovascular (5).

Nearly 50% of all original PMA's submissions (not including supplements) were Cardiovascular, with the rest evenly distributed among other specialties. While only 6 / 46 De Novo devices were implantable, nearly half (47%) of all PMA's were implantable devices.

Why it matters?

The field of Cardiovascular medicine continues to garner significant investment and rapid technological advancements as cardiovascular disease remains a leading cause of morbidity and mortality worldwide, and tech advancements are enabling new minimally-invasive implantables and procedures for high-risk patients in Cardiovascular, Gastrointestinal and Urology, and other medical specialties. Further, significant growth in software and AI-enabled technologies is contributing to a new wave of devices across Radiology and general imaging, explaining why the most common product type cleared in the US in 2023 was Product Code LLZ – Image Processing Systems for Radiology – with 88 510(k) clearances.

Over 50% of all medical device clearances and approvals in the United States (56%) come from US-based manufacturers, with Asia Pacific following suit with China (18%) and South Korea (8%) in 2nd and 3rd. Non-US companies shy away from Pre-Market Approvals (PMA) with 30/35 PMAs in 2023 submitted by US-based manufacturers, and US-based companies lead the charge in developing innovative devices that address unmet needs, with 33/46 De Novos granted to US-based companies, only followed by 4 from Israel.

Why it matters?

This underscores the dominance of US-based manufacturers in securing medical device clearances and PMAs, highlighting the US as a hub for innovative medical technology. It suggests the strategic advantage of being US-based or partnering with US companies for navigating regulatory processes and

pioneering advancements in medical technology. This is crucial for strategic planning, especially for non-US firms aiming to compete or collaborate in this highly innovative and regulated market. The growing prominence that Asia Pacific plays in development of FDA-cleared devices might also suggest that the US is a second wave market for those companies based in China and South Korea.

Mid and Large Cap multinationals continue to lead the charge in total 510(k) clearances and pre-market approvals (PMA) per company with 10 companies (e.g. Siemens, Abbott, Medtronic, Boston Scientific, etc.) representing more than 10% of the volume of all 510(k) devices cleared in the United States in 2023. The story is even more true for PMA, with the majority led by Medtronic, Abbott, Boston Scientific, Terumo, and others, but reputable emerging ventures such as LimFlow (acquired by Inari Medical) also changed the game in 2023 for high-risk patients. De Novos interestingly, are represented by a diverse basket of emerging ventures with some established multinationals taking a swing at breakthrough technologies.

Why it matters?

The high rigor for safety and effectiveness requirements for PMA devices warrants significant development, capital, and resource needs to bring these often implantable and high-risk devices to patients – for which established multinationals are more likely to have the budget, know-how, talent, clinical-network, risk-appetite, and capital on hand to execute. By their DNA, it is no surprise that De Novo devices continue to be led by a diversity of emerging ventures as these ventures often exist and secure funding to tackle unmet needs and innovate novel solutions.

The FDA electronic Submission Template and Resource (eSTAR) mandate went into effect October 2023 with a purpose to streamline and help automate the medical device submission review process at the risk of stripping MedTech companies of a collaborative submission preparation process**.** All medical device companies entering the United States are now required to submit 510(k) submissions using eSTAR. Despite the overwhelming concern for eSTAR, only 40% of respondents felt their regulatory affairs organization was ready for eSTAR and only 43% were prioritizing the regulatory process change.

Strategic Guidance: 2024 and Beyond

Increased Emphasis on Digital Transformation and AI Integration: In 2024, we anticipate a surge in the integration of digital transformation strategies and artificial intelligence within the MedTech sector. To succeed, CEOs and executives should prioritize investments in AI-driven analytics, machine learning for predictive modeling, and digital platforms that enhance patient care and operational efficiency. Establishing partnerships with tech firms to leverage their expertise in AI and digital health solutions, and use of AI and cloud in operations, is essential.

Adapting to Regulatory Changes with a Focus on Digital Health: As the regulatory environment for digital health products continues to evolve, MedTech companies must stay ahead of changes to ensure compliance and capitalize on new opportunities. This involves closely monitoring updates from regulatory bodies, such as the FDA, and adapting product development and compliance strategies accordingly. Executives should consider establishing resolute regulatory teams focused on digital health, investing in regulatory technology solutions to streamline compliance processes, and engaging in early dialogue with regulatory agencies to clarify requirements for digital health innovations.

Greater Investment in AI/ML Technologies: The continued growth of AI and ML applications in MedTech calls for significant investment in these areas. CEOs should foster innovation by allocating resources to R&D in AI/ML, engaging in strategic partnerships with AI-focused startups, and staying informed on regulatory guidelines for AI-enabled devices to ensure compliance and foster innovation responsibly.

Leveraging Real-World Evidence (RWE) for Regulatory and Market Access Strategies: The use of real-world data and evidence will play a crucial role in regulatory submissions and market access strategies. MedTech leaders should invest in systems and expertise to collect, analyze, and leverage RWE, aligning product development and post-market surveillance strategies with real-world outcomes.

Rapid Adoption of eSTAR for Regulatory Submissions: With the FDA's eSTAR mandate fully in effect, MedTech companies need to adapt rapidly. Executives should focus on training their teams on the eSTAR platform, streamlining document preparation processes, and ensuring their submissions meet the new digital format requirements. Investing in eSTAR-ready software solutions and consulting services can facilitate a smoother transition.

Embracing Breakthrough Device Designation and Expedited Pathways: As we move into 2024, MedTech companies with De Novo and PMA pathway devices should actively pursue FDA's Breakthrough Device Designation for qualifying innovative technologies. This necessitates a strategic approach to product development, ensuring that devices not only meet critical healthcare needs but also align with the FDA's criteria for significant clinical benefits. Executives should focus on building a cross-functional team specialized in navigating the Breakthrough pathway, engaging early and frequently with the FDA, and preparing robust clinical and healthcare economics evidence to support expedited review and market access. FDA and CMS should continue to align and explore expansion of the TCET after initial learnings.

Heightened Focus on Cybersecurity Measures: As digital health technologies become more prevalent, the importance of robust cybersecurity frameworks cannot be overstated. Leaders should implement comprehensive cybersecurity strategies, conduct regular security audits, and foster a culture of cyber hygiene within their organizations. Collaboration with cybersecurity experts to stay ahead of potential threats is recommended.

Strategic Planning for Decentralized Clinical Trials (DCTs): With the FDA endorsing decentralized clinical trials, companies should adapt their clinical development strategies to include DCT methodologies. This involves leveraging digital tools for remote patient monitoring, ensuring data integrity and compliance with regulatory standards, and enhancing patient engagement and recruitment strategies.

2023 Spotlights

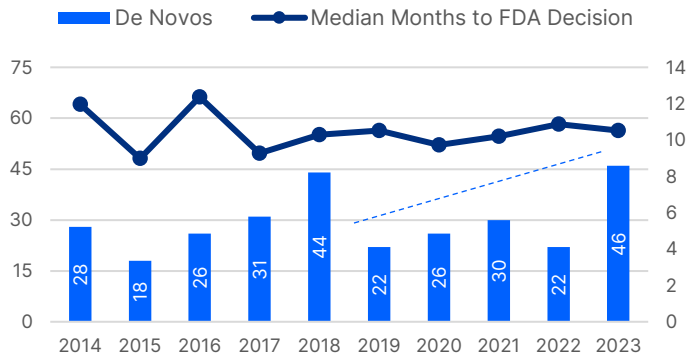
A Record Year for MedTech Innovation

2023 was a historic year for medical device innovation including guidance updates, new policies, and volume of novel medical devices entering the US market, further advancing the United States and FDA as the most innovation-friendly regulatory pathway and market. We highlight milestones demonstrating the advancements in innovation, from De Novo devices to the Breakthrough Device Designation and the promise of accelerated reimbursement coverage for emerging technologies through the Proposed CMS TCET reimbursement pathway.

De Novo Devices Boom 2X to Record Height

The number of novel products entering the US market continues to bloom as new diagnostics and treatments are reviewed and approved by the FDA for market via innovation-friendly pathways. The number of De Novo clearances increased 2.5 times between 2022 and 2023 from 22 to 46 devices granted De Novo clearance. This is a significant year-over-year increase over 2021 as well, in which 30 De Novos were authorized for market, suggesting an increasing trend in innovative devices.

Exhibit 1: The Second Rising Wave of De Novos in the United States 2019-2023



While innovation has manifested itself in prior years in concentrated medical specialties with heavy emphasis on innovation and capital to support from private venture and strategics alike, including cardiovascular and radiology, 2023 observed more De Novo clearances in Gastroenterology and Urology (6), Microbiology (5), General Hospital (5), followed by the regulars of Cardiovascular (5) and Radiology (4). Overall, De Novos are dispersed across medical specialties, with the remaining 18 devices being reviewed by seven other review panels.

Examples of diverse spread of De Novos include:

- **AXIOS Stent and Electrocautery-Enhanced Delivery System**: A device intended for transgastric or transduodenal endoscopic drainage of the gallbladder, demonstrating innovation in non-surgical treatment options for gallbladder.

- **Simple 2 Test:** An in vitro diagnostic system designed for self-collecting and testing specimens in home settings or similar environments for the detection of nucleic acids from non-viral microorganisms causing sexually transmitted infections, reflecting the growing trend in patient-centric diagnostic solutions.

- **Revi System**: An implanted tibial electrical urinary continence device aimed at treating overactive bladder symptoms through electrical stimulation of the tibial nerve, showcasing advancements in neuromodulation therapies.

- **Ruthless Spine RJB**: An intraoperative surgical angle measurement tool that attaches to surgical instruments to measure the angle relative to a vertical plumb line, indicative of innovations in surgical instrumentation and technique precision.

When it comes to where the innovation hubs are concentrated for novel devices, 75% of De Novo devices came from US-based companies whereas the second and third leading sources of innovation were Israel (4) and Ireland (3) .

These findings indicate a diverse range of medical specialties benefiting from the De Novo pathway, with notable concentrations in Gastroenterology and Urology, and Cardiovascular devices leading the way. This diversity reflects the pathway's role in facilitating market access for innovative medical devices that lack a clear predicate but promise significant benefits to patient care in a variety of clinical areas.

For regulatory professionals, CEOs, and venture capitalists alike, this spread underscores the opportunity across a broad spectrum of medical fields to innovate and bring novel devices to market through the De Novo pathway. It highlights the potential for investment and development in areas with a high rate of De Novo approvals, suggesting these are areas of unmet medical need or significant technological advancement

FDA Breakthrough Device Designation Program and its Interface with the Proposed CMS TCET Reimbursement Pathway

The FDA Breakthrough Device Designation Program is a regulatory initiative and voluntary program designed to expedite the development and review of innovative medical devices that offer significant advancements in the diagnosis or treatment of life-threatening or debilitating conditions. This program aims to provide patients with quicker access to breakthrough technologies while maintaining the rigorous safety and effectiveness standards of the FDA. This summary explores the purpose, trends, statistics, and the pros and cons of the FDA Breakthrough Device Designation program, along with its relationship with the proposed CMS TCET reimbursement pathway.

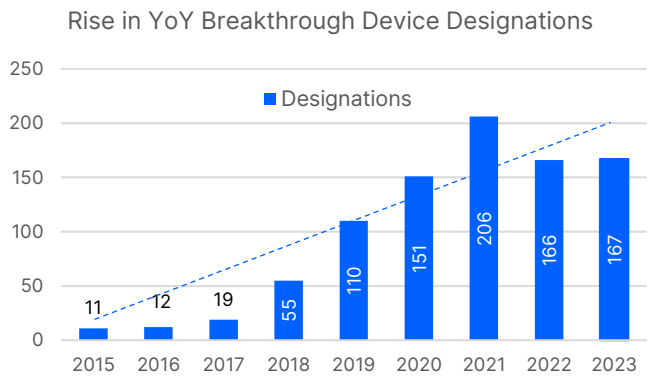
The primary purpose of the FDA Breakthrough Device Designation Program is to accelerate the approval process for devices that address unmet medical needs. The program fosters collaboration between the FDA and device developers, facilitating more efficient communication and guidance throughout the regulatory process. Trends indicate a growing number of applications for Breakthrough Designation, with the FDA reporting over 921 devices designated by year end including those from the Expedited Pathway. As of December 2023, a total of 95 breakthrough designated devices obtained market authorization ever since the program's inception, marking a historic growth in breakthrough technologies available to patients and healthcare providers on the market.

In 2023 alone, 29 Breakthrough Devices were authorized for market by the agency, reflecting the industry's eagerness to bring groundbreaking technologies to market swiftly.

In recent years, the FDA has experienced a surge in Breakthrough Device Designation applications, showcasing the industry's increasing reliance on this program. The statistics reveal a notable rise in the number of granted designations, reflecting the FDA's commitment to fostering innovation. As of 2023, the program has witnessed a 30% year-over-year increase in designations, demonstrating its significance in the medical device landscape.

The FDA Breakthrough Device Designation Program comes with several advantages. For developers, the program offers a streamlined regulatory pathway, reducing time to market and development costs. Patients benefit from earlier access to transformative technologies that can potentially improve their quality of life. However, challenges include the risk of premature market entry, with concerns about the long-term safety and effectiveness of devices granted breakthrough status. Striking the right balance between speed and thorough evaluation remains a challenge for regulatory authorities.

Exhibit 2: Rise in Year-over-Year Breakthrough Device Designations



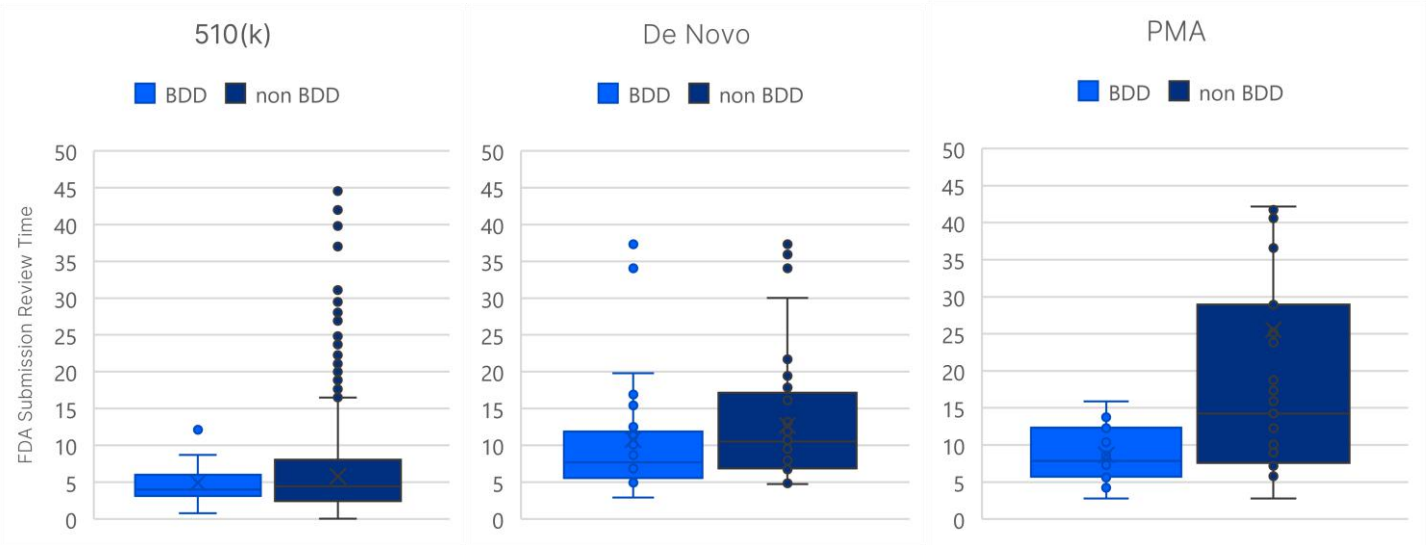
Does Breakthrough Device Designation deliver value-benefit for all devices, or only some?

Overall, participants in the Breakthrough Device Program applaud their experience for the more intimate dedicated support and engagement with the FDA in the program. For some ventures that chose to publicly report their designation, it can provide brand awareness in a pre-FDA stage without inappropriately marketing their device in the United States.

On the other hand, some manufacturers and investors call into question the benefit the program brings in ensuring more predictable and expedited access to the market. We examined one parameter to evaluate this, investigating the time it takes for a medical device to obtain a positive FDA decision after submitting their 510(k), De Novo, or PMA application as compared to the benchmarks for time from submission to positive FDA decision in 2023.

Based on our findings, 75% of the 29 De Novo and 13 PMA Breakthrough devices that obtained FDA market authorization benefited from an expedited decision compared to 2023 benchmarks for De Novos and PMAs. 75% of Breakthrough De Novos received FDA granting within 11.9 months compared to non-Breakthrough devices at 16 months, and 75% of Breakthrough PMA devices received premarket approval 12.3 months compared to 28.9 months for non-Breakthrough PMAs.

Exhibit 3: FDA Review Time for Breakthrough Designated Devices (BDD) vs. non-designated Devices (non BDD) that received 510(k) Clearance, De Novo granting, or Pre-market Approval (PMA)



Median Time to FDA Decision (months)	510(k)	De Novo	PMA
Breakthrough Devices (2021-2023)	4.0 months	7.7 months	7.8 months
Non-Breakthrough Devices (2023)	4.5 months	10.5 months	14.3 months
Months Gained with Breakthrough	**+0.5 months**	**+2.8 months**	**+6.5 months**

While early experience and data for Breakthrough Designated De Novo and PMA devices appears to suggest time savings of 2.8 and 6.5 months respectively on average, there is limited benefit for 510(k)s that are breakthrough designated. These devices might more predictably earn a 510(k) clearance within five months of FDA submission, but the overall time benefit of 0.5 months is limited. Manufacturers of 510(k) devices must weigh other considerations such as, if they are a new venture with a first-time product, would the company benefit from the more interactive and "priority lane" experience engaging with the FDA as a breakthrough device verse pursuing a normal 510(k) pathway as an experienced device manufacturer.

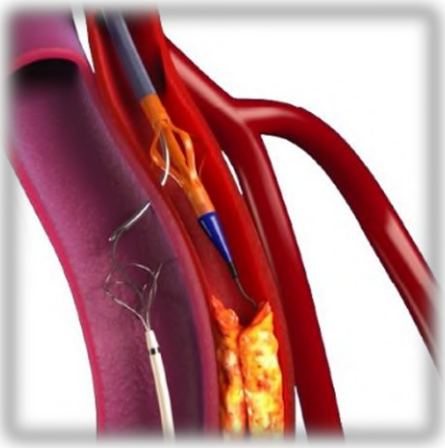
With this insight, we acknowledge that one limitation of this analysis is we are comparing a sample of multiple years of Breakthrough Devices authorized in the market compared to 2023 benchmarks. We do this because the sample of FDA approved Breakthrough devices is limited and concentrated in recent years. Another consideration for future analysis is whether certain medical specialty panels have more veteran experience reviewing innovative breakthrough devices, contributing to more expedited review than other breakthrough device product codes and specialties.

"Companies should shift from considering Breakthrough as a standalone choice – because of its prior significant reimbursement benefit – to it being one weighted factor in an integrated regulatory strategy. The data suggests the regulatory strategy considers FDA application type, additional FDA programs (e.g., TAP), device type and more"

Kwame Ulmer

Managing Partner, MedTech Impact Partners

Examples of 3 Breakthrough Designated Devices that obtained FDA market authorization in 2023



Detour System by Endologix, LLC:

- **Breakthrough Designation**: Granted in 2022
- **FDA Pathway**: Pre-Market Approval in 2023
- **FDA Review Time**: 7.9 months to PMA
- **PMA Benchmark Review Time:** 10.5 months

Outcome: The Detour System, a novel endovascular stent graft system for the treatment of abdominal aortic aneurysms, received Breakthrough Designation in 2022. This designation facilitated a streamlined regulatory pathway, leading to a successful Pre-market Approval in 2023 within 8 months of submission, rapidly accelerated compared to the FDA Review Time benchmark for PMAs of 14.3 months. The accelerated approval allowed for the timely availability of this innovative solution to patients in need of percutaneous revascularization but who may be considered suboptimal candidates for surgical or alternative endovascular treatments.

Traumatic Brain Injury (TBI) Test by Abbott Laboratories:

- **Breakthrough Designation**: Granted in 2021
- **FDA Pathway**: FDA 510(k) Clearance in 2023
- **FDA Review Time:** 3.0 months to 510(k)
- **510(k) Benchmark:** 4.4 months to 510(k)

Outcome: Abbott Laboratories' Traumatic Brain Injury (TBI) Test, designed for rapid and accurate diagnosis of traumatic brain injuries, obtained Breakthrough Designation in 2021. Under-diagnosis of traumatic brain injuries is a significant unmet need, with 5 out of 10 concussions being undetected. The device navigated the regulatory landscape efficiently, securing FDA 510(k) clearance in 2023.

Stanza by Swing Therapeutics, Inc.:

- **Breakthrough Designation:** Granted in 2021
- **FDA Pathway:** De Novo Clearance in 2023
- **FDA Review Time:** 5.6 months to De Novo
- **De Novo Benchmark Review Time:** 10.5 months

Outcome: Swing Therapeutics' Stanza, a digital behavior therapeutic platform indicated for treatment of fibromyalgia symptoms and designed to assist individuals in managing and coping with chronic pain, secured Breakthrough Designation in 2021. This recognition helped expedite the FDA regulatory review process – resulting in an FDA submission review time of 5.6 months, notably 5 months faster than the median De Novo review time. Stanza's De Novo underscored the program's flexibility in accommodating digital therapeutics, offering a new avenue for patients seeking alternative pain management solutions.

Relationship with CMS TCET Reimbursement:

The proposed CMS TCET (Transformative and Continuous Innovation and Emerging Technologies) reimbursement pathway complements the FDA Breakthrough Device Designation Program by addressing the economic aspect of market access. The integration of a reimbursement pathway acknowledges the need for an integrated approach to facilitate both regulatory approval and reimbursement processes. This alignment encourages developers to invest in breakthrough technologies by providing a more predictable and sustainable reimbursement framework.

The FDA Breakthrough Device Designation Program plays a pivotal role in expediting the development and approval of transformative medical technologies. Its alignment with the proposed CMS TCET pathway signifies a comprehensive approach to innovation, addressing both regulatory and economic considerations. While the program's pros include accelerated market access and improved patient outcomes, careful evaluation and continued monitoring are essential to mitigate potential cons and ensure the long-term safety and effectiveness of breakthrough devices

Digital Transformation, Artificial Intelligence, and the Boom for Generative Technologies

In 2023, the MedTech industry witnessed a pivotal shift towards the integration of Artificial Intelligence (AI) and Machine Learning (ML) within its operations and product offerings. This transformation has been prominently showcased at significant industry conferences such as the AdvaMed MedTech Conference, where Generative AI commanded the stage, underlining its growing influence and potential within the sector. As we navigate through the implications and strategic impacts of these advancements, it's crucial to understand the key topics that have shaped the MedTech landscape, including regulatory guidance, the advent of AI/ML-enabled medical devices, and the modernization of clinical practices through digital solutions.

FDA, MHRA, and Health Canada Regulatory Frameworks

A significant development in 2023 was the publication of guiding principles by regulatory bodies such as the FDA, MHRA, and Health Canada. These principles aim to streamline the development and oversight of AI/ML-enabled medical devices. Predetermined Change Control Plans have been emphasized, allowing for a structured approach to managing updates and modifications in AI/ML algorithms post-market launch. This initiative is designed to ensure that continuous learning algorithms maintain their efficacy and safety over time, addressing one of the primary challenges in the dynamic field of AI/ML.

Furthermore, the introduction of Good Machine Learning Practices (GMLP) marks a significant step towards standardizing the development process of AI/ML-enabled devices. These guidelines serve as a comprehensive framework for developers, ensuring that devices are designed with a focus on reliability, safety, and efficacy from inception through post-market surveillance.

The Rising Tide of AI/ML-enabled Medical Devices

According to the FDA, over 700 AI/ML-enabled medical devices were authorized by year end, showcasing the rapid adoption and trust in these technologies within healthcare. This proliferation underscores the potential of AI/ML in enhancing diagnostic accuracy, personalizing treatment plans, and improving patient outcomes. The strategic implication for MedTech executives is clear: investment in AI/ML capabilities is no longer optional but a necessity to stay competitive and relevant in the evolving healthcare landscape.

Decentralized Clinical Trials (DCT) and Cybersecurity

The Draft FDA Guidance on Decentralized Clinical Trials (DCT) represents another pivotal shift, advocating for a more flexible, patient-centric approach to clinical studies. Leveraging digital technologies to conduct trials remotely offers the potential to reduce costs, improve patient engagement, and accelerate the development timeline for new medical technologies.

Parallelly, with the increasing reliance on digital technologies, the draft guidance on cybersecurity for 2024 has become ever more critical. As MedTech firms continue to integrate AI/ML into their devices and operations, ensuring the security and integrity of patient data and device functionality against cyber threats is paramount.

Modernizing Good Clinical Practices

The modernization of Good Clinical Practices through digital solutions is a testament to the industry's commitment to leveraging technology for operational efficiency and efficacy. Digital solutions offer a way to streamline clinical trial processes, improve data quality, and facilitate regulatory compliance, all while maintaining patient safety at the forefront.

Adopting AI-enabled Solutions in MedTech Regulation and Regulatory Operations:

Incorporating AI-enabled solutions into pre-market and post-market regulatory affairs and product lifecycle activities presents MedTech executives with unparalleled strategic opportunities, needs, and implications for capital investment. The integration of AI technologies can significantly streamline regulatory processes, reduce time-to-market, ensure compliance with evolving standards, and enhance post-market surveillance efficiency. By automating routine tasks, AI

can free up valuable human resources to focus on more complex regulatory challenges, thus optimizing operational efficiencies and reducing overhead costs.

Investing in AI-enabled solutions facilitates a more dynamic response to regulatory changes, enabling MedTech companies to adapt their strategies swiftly and efficiently. For instance, AI can analyze vast datasets to predict regulatory trends, identify potential compliance issues before they arise, and optimize product development pathways. This proactive approach not only mitigates risks but also accelerates the pace at which new innovations reach the market, thereby enhancing competitive advantage.

Moreover, the use of AI in post-market surveillance can revolutionize the way adverse events are monitored and reported, ensuring real-time data analysis and faster implementation of necessary corrective actions. This not only improves patient safety but also reinforces the company's reputation and trustworthiness in the market.

The strategic implication for MedTech executives is clear: the investment in AI not only addresses immediate operational needs but also positions the company for future growth and innovation. It enables a shift from reactive regulatory compliance to a strategic, forward-thinking approach that leverages data for competitive advantage. As regulatory bodies increasingly recognize the value of AI/ML in healthcare, companies at the forefront of adopting these technologies will be better positioned to navigate the regulatory landscape, capitalize on market opportunities, and lead in the innovation of healthcare solutions.

Looking Forward in 2024 and beyond

As we look towards 2024, the strategic implications of these developments for MedTech executives are multifaceted. The ongoing evolution of regulatory landscapes necessitates a proactive approach to compliance and innovation. The burgeoning number of AI/ML-enabled medical devices emphasizes the importance of investing in these technologies, not just for product development but also to enhance operational efficiencies and patient outcomes.

Moreover, the emphasis on cybersecurity and the modernization of clinical practices through digital solutions highlights the critical role of technology in safeguarding patient data and improving the efficiency of clinical trials. These advancements present both opportunities and challenges for MedTech firms, necessitating a balanced approach to innovation, regulation, and patient safety.

In conclusion, the year 2023 has set a precedent for the rapid integration of AI/ML in the MedTech sector, driven by regulatory advancements, the proliferation of AI/ML-enabled devices, and the digital transformation of clinical practices. As we move into 2024, MedTech executives must navigate these developments strategically, leveraging the potential of AI/ML while ensuring compliance, cybersecurity, and the continuous improvement of patient care. The journey towards fully realizing the benefits of AI/ML in healthcare is ongoing, but the foundations laid in 2023 offer a promising path forward.

AI in Regulatory Transformation

Artificial Intelligence (AI) and Machine Learning (ML), along with enabling exponential technologies including Cloud, can revolutionize medical device company's product lifecycle and Regulatory Information Management (RIM) systems by enhancing their capability to process, analyze, and predict regulatory outcomes. Integrating AI/ML in RIM systems offers MedTech companies' numerous benefits that CXO's and regulatory leaders must take identify case studies for and invest in projects and solutions that enable the company to maximize on these technological advancements early.

Some of these case examples and benefits include:

Automated Data Processing: AI algorithms can automate the extraction and categorization of regulatory data from various sources, increasing efficiency and reducing manual labor.

Predictive Analytics: ML models can predict regulatory changes by analyzing patterns in historical data, helping companies to proactively adapt to new requirements.

Improved Compliance: AI/ML can help identify potential compliance risks by analyzing large datasets and flagging anomalies or deviations from regulatory standards.

Efficient Submission Preparation: AI tools can streamline the preparation of regulatory submissions by auto-generating documents based on templates and pre-filled data, ensuring consistency across applications.

Regulatory Intelligence: AI systems can scan global regulatory databases and provide real-time updates on legislation changes, guideline amendments, and other critical regulatory information.

Risk Assessment: ML can enhance risk assessment processes by modeling potential outcomes and impacts of regulatory decisions, aiding in strategic planning.

Data Quality Control: AI can improve data quality by continuously monitoring data entries for errors or inconsistencies and correcting them in real-time.

Enhanced Search Capabilities: Natural Language Processing (NLP) can be used to search and retrieve relevant regulatory information quickly, saving time for regulatory affairs professionals.

Language Translation: AI can assist in translating regulatory documents, labeling, and submissions, facilitating easier entry into international markets.

Training and Simulation: ML algorithms can be used to train regulatory affairs staff by simulating different regulatory scenarios and outcomes, providing an interactive learning experience.

Implementing AI/ML within RIM systems can transform regulatory affairs into a strategic asset for MedTech companies, enabling them to maintain a competitive edge through efficient regulatory processes and improved decision-making. It is crucial, however, that these systems are designed with careful consideration of the regulatory landscape, ensuring they meet the stringent requirements of healthcare regulation.

"If you can begin to see AI as a kind of friend, like a co-pilot, as someone or something who can enhance your life and make you a better, smarter, quicker, more decisive individual, then you will begin to reap the benefits.

Human intelligence should be viewed as a means to enhance human ability. When AI is viewed as a friendly co-pilot, it does not replace human intelligence but rather advances our overall intelligence and human ability."

Dr. Dhriti Roy

Vice President, Regulatory Transformation, Essenvia

FDA eSTAR

On October 1st, 2023, the industry embraced one of the FDA's principal digital transformation initiatives called eSTAR (Electronic Submission Template for Medical Device 510(k) Submissions) as what was once a voluntary program was mandated overnight for all 510(k) submissions, unless exempted.

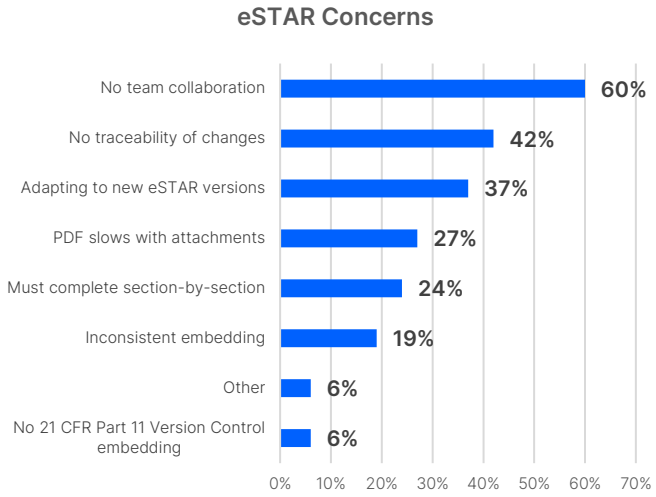
Beyond October, 510(k) submissions are required to be submitted using the interactive PDF form designed to guide applicants through the process of creating a comprehensive medical device submission. It ensures the provision of necessary details, complements internal review processes, and offers a standardized format for accessibility. eSTAR automates submission aspects, reducing the need for Refuse to Accept (RTA) reviews. It includes built-in databases, auto-fills information, and collects data in a structured format, streamlining FDA processing. eSTAR is mandatory for 510(k) submissions and voluntary for other types. Submission timelines, user fees, and review processes are detailed, aiming to enhance the quality and efficiency of premarket reviews.

In 2023, Essenvia partnered with Informa MedTech Series to survey 67 MedTech regulatory professionals for which nearly 50% were director level or above. The purpose was to survey the landscape and determine the degree of awareness and preparedness of industry to adapt to the eSTAR mandate.

Immediately prior to October, 9 out of 10 regulatory professionals had some awareness of eSTAR, but only 1 in 3 had used the eSTAR interactive PDF to complete a 510(k) submission while the program was voluntary.

With this limited experience among respondents, it might come to no surprise that 78% of regulatory professionals surveyed reported a degree of concern about eSTAR becoming the standard for submission preparedness and authoring.

It is evident that the regulatory community perceives that the primary benefit of eSTAR is a clearer understanding of information required by the FDA for submissions, but the majority (60%) are markedly concerned that the interactive eSTAR PDF template, albeit interactive, restricts freedom to collaborate, can be slow to respond, does not permit easy change tracking (42%), and is painful to track new version releases of eSTAR (37%).



Despite the overwhelming concern for eSTAR, only 40% of respondents felt their regulatory affairs organization was ready for eSTAR and only 43% were prioritizing the regulatory process change. For those that were prepared for eSTAR transition, the most common preparation step was participation in the FDA eSTAR pilot program, by 18% of organizations. Other practices included forming an eSTAR transition task force or specialized team and appointing an eSTAR champion coordinator (each at 15%) and implementing new Standard Operating Procedures and engaging a third-party regulatory consultant (each at 12%). However, a significant 45% have not implemented any of these practices, indicating a potential readiness gap within Medtech regulatory affairs organizations.

Moving forward, we anticipate eSTAR to continue to rollout for adoption among other FDA approval pathways, including PMA in 2024 and beyond, with further harmonization expected with other aligned market regulatory agencies including Health Canada, UK MHRA, and more.

Download the full report here for more information

Transition Beyond Pandemic

One of the most significant policy changes of 2023 impacting the in vitro diagnostic segment of MedTech was the transition of regulation for COVID-19 testing from an Emergency Use Authorization (EUA) to a regulated pathway. Over 21 devices were successfully transitioned from EUA to traditional marketing authorization.

For MedTech companies, the final guidance documents pertaining to COVID-19 underline the importance of staying agile and compliant in a dynamic regulatory environment. They also emphasize the need for strategic planning around product lifecycle management, from emergency use authorization to full market authorization transitions, ensuring that products can continue to meet regulatory requirements and serve public health effectively

Strategic Insights and Implications of Guidance Documents pertaining to COVID-19 pandemic include:

- **Adaptation to Public Health Needs**: These documents highlight the FDA's flexibility and responsiveness to the ongoing public health needs related to the COVID-19 pandemic, particularly in areas of sterilization, disinfection, and emergency use of medical devices.
- **Guidance on EUAs**: The transition plans for medical devices issued under EUAs reflect a strategic move towards normalizing regulatory processes post-pandemic. This transition guidance is critical for companies that have developed or distributed products under EUA, as it outlines the pathway to regular approval or what steps need to be taken as the public health emergency status evolves.
- **Focus on Safety and Effectiveness**: By issuing final guidance on these topics, the FDA emphasizes the continued importance of ensuring the safety and efficacy of medical devices used in the context of COVID-19. This serves as a reminder for companies to rigorously maintain compliance with regulatory standards, even as they adapt to the changing landscape.
- **Preparation for Future Public Health Emergencies**: These guidance documents collectively suggest that MedTech companies should prepare for future public health emergencies by developing robust plans for rapid response, including the ability to quickly adapt manufacturing and distribution.


Insights

Regulatory Insights

Identifying and choosing a regulatory pathway is a critical step for MedTech executives in determining the strategy and path to market in the United States that can affect product development, clinical trial, and go-to-market decisions, as well as capital burn.

We uncover significant variations in the FDA review process for the minimum, median, and maximum times from device submission to FDA decision segmented by medical device approval pathways—510(k), De Novo, PMA (Pre-Market Approval), and PMA Supplements—that are essential for regulatory professionals and executives to account for in determining a US regulatory strategy.

The 510(k) pathway, used for devices that are substantially equivalent to those already on the market, shows a swift median decision time of 4.5 months. This pathway's agility is crucial for companies looking to bring innovations to market that build on existing technologies. However, the broad range from 0.03 to 45.2 months indicates a potential for extended review times based on specific device complexities or additional data requirements.

The De Novo pathway, designed for novel devices without a clear predicate, reveals a longer median decision time of 10.68 months. This reflects the inherent challenges and additional scrutiny applied to new types of devices, emphasizing the importance of thorough pre-submission engagement and robust data packages for regulatory professionals.

PMA, the most stringent pathway for high-risk devices, shows the longest median time to decision at 14.47 months, with some processes extending beyond 134 months. This underscores the critical need for strategic planning, comprehensive clinical data, and ongoing communication with the FDA to navigate this pathway successfully.

PMA Supplements, dealing with modifications to already approved devices, exhibits the shortest median review time of 0.93 months. This efficiency is pivotal for companies making incremental improvements to their devices, allowing for rapid adoption of innovative technologies and enhancements.

For regulatory professionals and executives, these insights highlight the importance of selecting the appropriate pathway based on the device's novelty, risk profile, and market strategy. Understanding the typical timelines and preparing for the variability in review times can significantly impact the success of bringing a medical device to market. This knowledge enables more accurate planning, resource allocation, and strategic decision-making in the highly regulated medical device industry

Exhibit 4: FDA 510(k) Clearances in 2023 (N = 3,300)

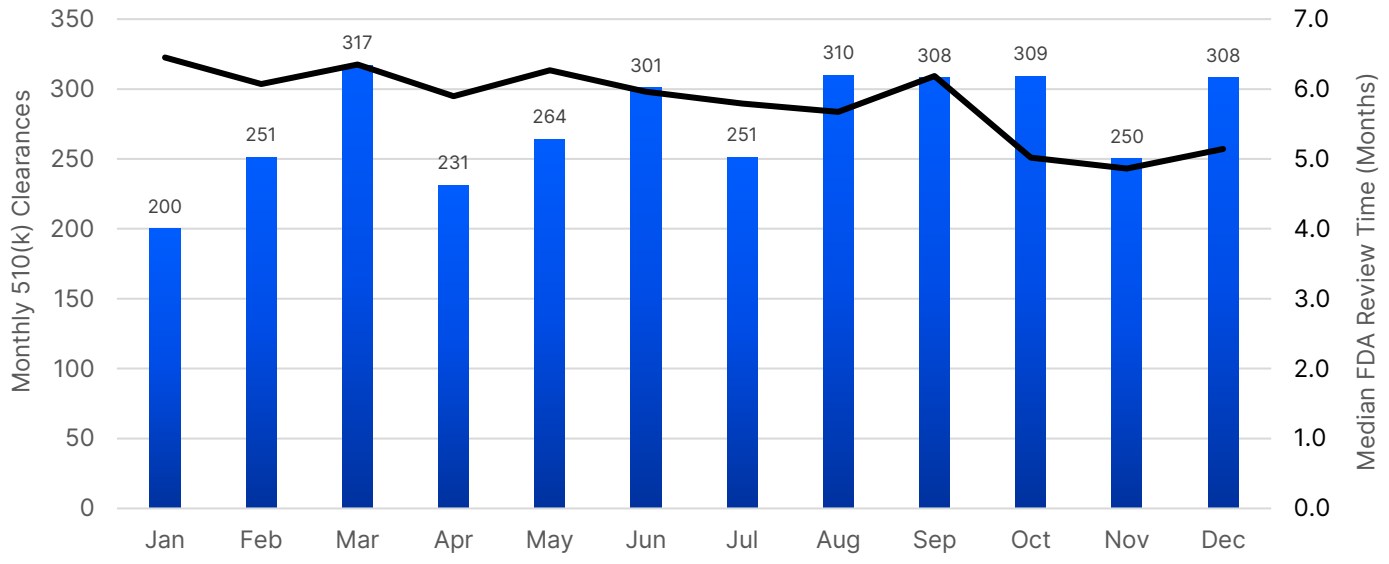


Exhibit 5: FDA De Novo market authorizations per month in 2023 (N = 46)

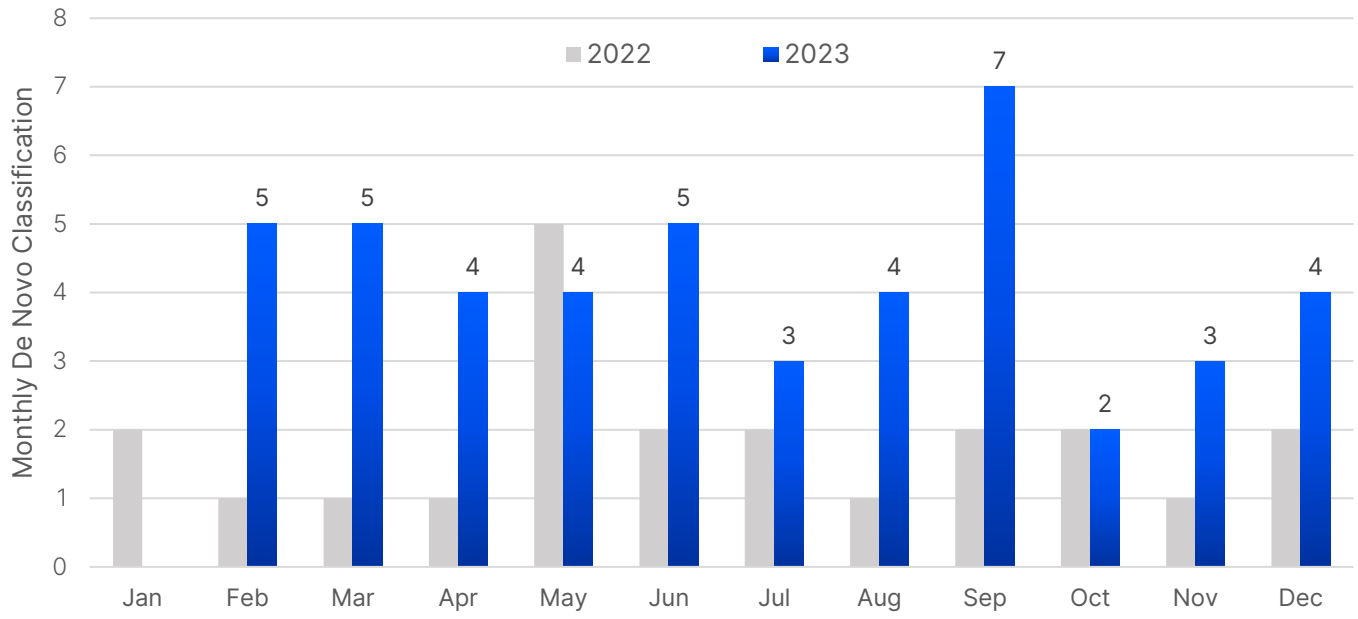


Exhibit 6: FDA Pre-Market Approvals (PMA) per month in 2023 (N = 35 PMA Originals)

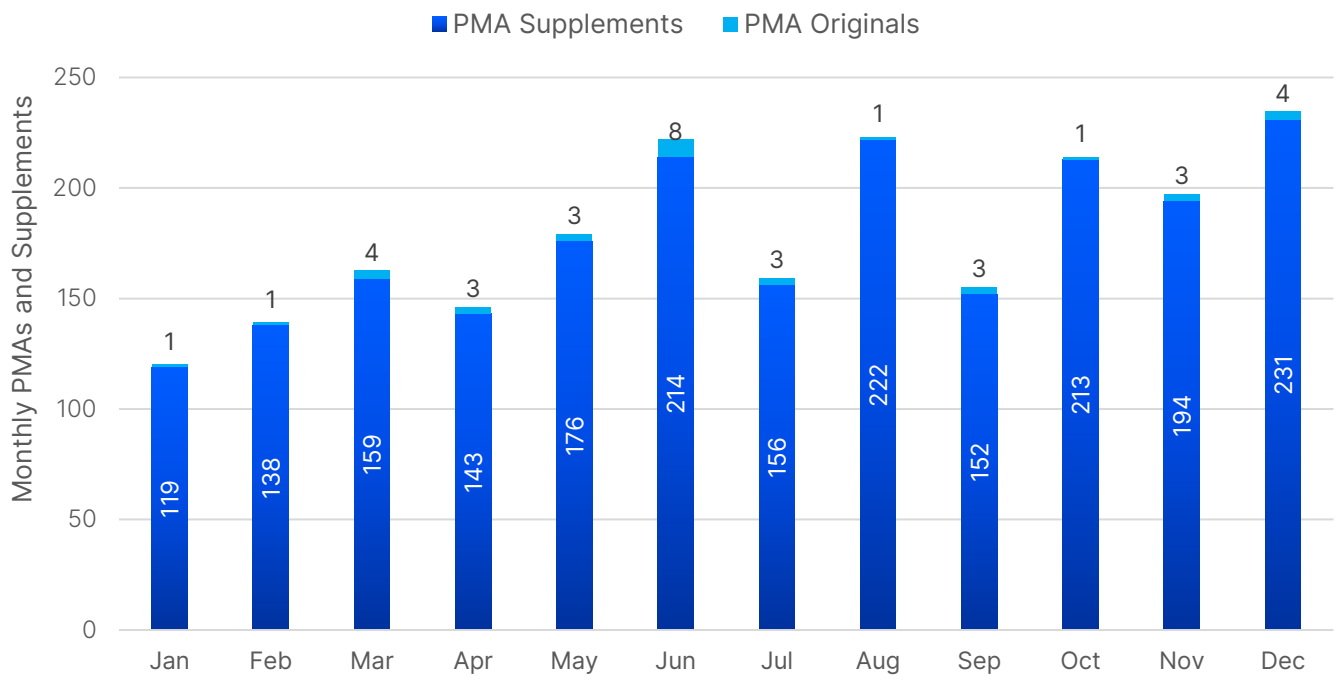
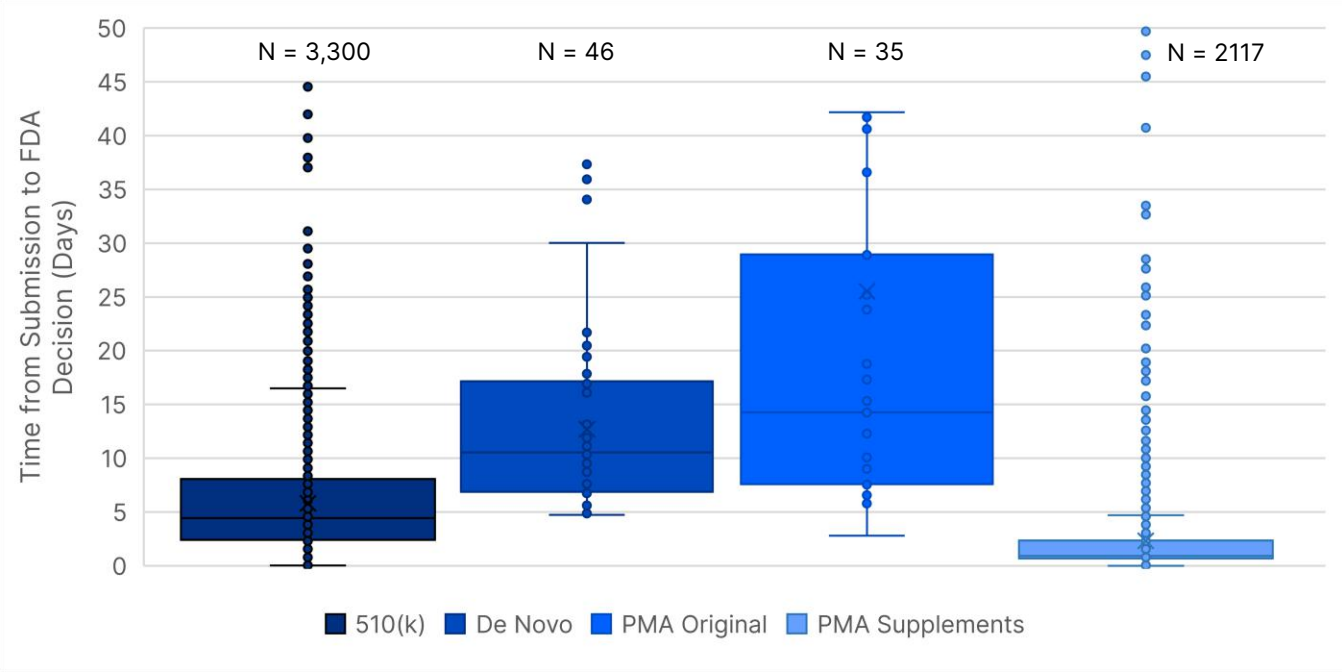


Exhibit 7: Time to FDA Decision (Days) for Medical Device Submissions in 2023 by Pathway



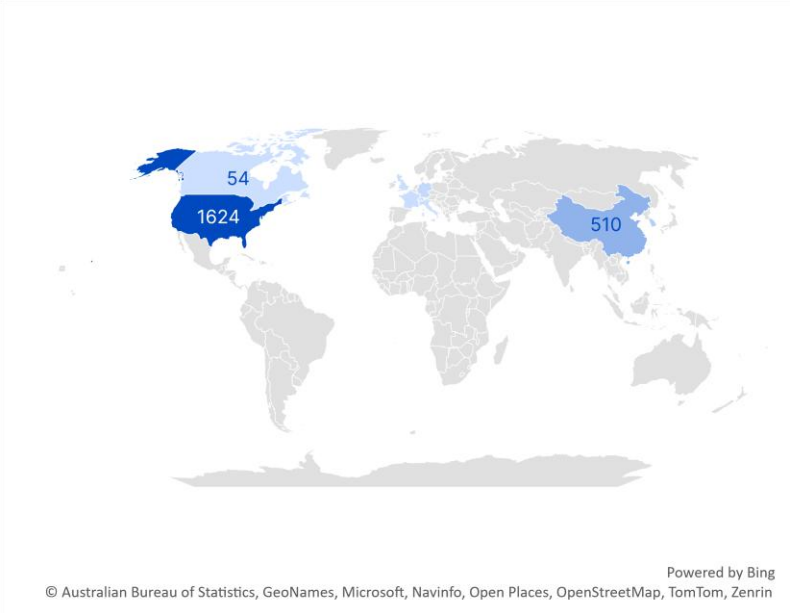
Note: Outliers greater than 50 months (132; 120; 72; 65) not displayed for PMA to enhance chart visualization

Table 1: Summary of Distribution of Time to FDA Decision in Months

FDA Review Time to MDUFA Decision	Minimum	Median	Maximum
510(k)	0.03 months	4.5 months	45 months
De Novo	4.7 months	10.5 months	37.3 months
PMA Original	2.8 months	14.3 months	132.4 months
PMA Supplements	0 months*	0.9 months	58.5 months

*PMA Supplements with market authorizations of 0-1 months typically participate in the 30-Day Notice supplement track, whereas supplements pursuing the Normal 180 Day Track, 135 Review Track, Special Tracks, Panel Tracks, and Real-Time Process typically earn authorization with 0.5 – 4.7 months.

Exhibit 8: (510(k) Clearances) Companies based in US, China, and South Korea led the charge (2023)



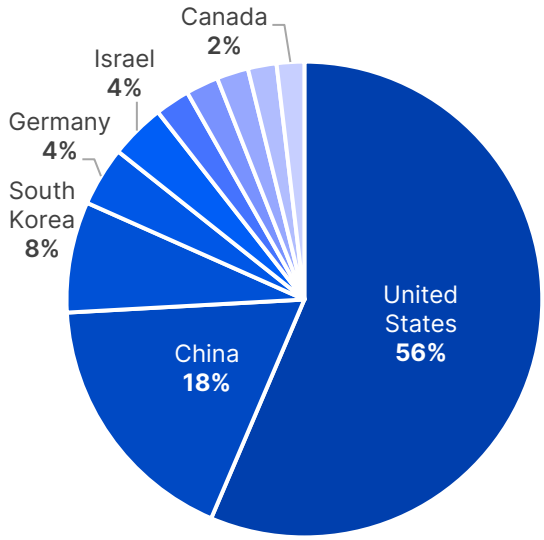


Exhibit 9: US companies lead Lion's Share for Innovative (De Novo) and High-Risk (PMA) Devices

De Novos	Country of Origin
33	United States
4	Israel
3	Ireland
2	United Kingdom
1	China
1	Finland
1	Canada
1	Germany

PMAs	Country of Origin
30	United States
2	United Kingdom
1	Germany
1	Israel
1	Switzerland

A Summary of Key Regulatory Insights and the Significance to MedTech Executives

- **510(k) Clearances impacted by eSTAR Mandate?** 3,300 medical devices obtained 510(k) clearance in 2023, exceeding the average baseline of approximately 3,000 device clearances year-over-year over the last decade. An interesting insight is the noticeable drop in the average FDA review time for 510(k) clearance for the months of October through December from 14 and 16 months in August and September respectively, to 13 and 12 months in October and November. Is this a positive consequence of the FDA's mandate going into effect on October 1st, 2023, for the eSTAR digital template to streamline the requirements and process for 510(k) clearances? While hopeful, this is unlikely to yet be observed as a trend for at least 6-9 months after the mandate when all companies have submitted via eSTAR – since it takes a median of 4 months for 510(k)'s to be cleared, we expect to start seeing a trend as early as February through June 2024. What we might being seeing is the direct benefit of CDRH successfully meeting its performance requirement by hiring and filling 100+ reviewer positions in which staffing gains reduced workflow burden and time to review.

- **De Novo Market Authorizations**: The De Novo authorizations exhibit a steady flow throughout the year with a notable peak in September. With 46 total authorizations, the De Novo route shows a consistent opportunity for introducing new types of devices without existing predicates.

- **PMA Approvals**: The data for Pre-Market Approvals (PMA) indicates a steady stream of approvals for PMA supplements, with original PMAs being less frequent but consistent. The highest number of PMAs and supplements are seen in June and December, suggesting potential strategic timings for submissions.

- **Time to FDA Decision**: The time to FDA decision varies significantly across pathways. The 510(k) pathway is the quickest, with a median time of 4.5 months, whereas De Novo and PMA Originals have longer median times of 10.5 and 14.3 months, respectively. This is crucial for strategic planning around submission timelines and market entry, particularly for 510(k)s where there is greater predictability.

- **Country of Origin**: The US leads in medical device clearances (56%), followed by China (18%) and South Korea (4%). For De Novo and PMA devices, US companies dominate with 33 and 30 submissions, respectively. This data underscores the competitive advantage and regulatory proficiency of US-based MedTech companies.

For a MedTech C-Suite executive, VP of Regulatory Affairs, or an Investor, these insights suggest several strategic implications:

- **Innovation Strategy:** The steady number of De Novo authorizations and the US's leadership position point towards a conducive environment for innovation. Companies should continue to invest in R&D for novel devices, especially those that could qualify for De Novo clearance. Considering the large APAC representation in the US, companies may reconsider Joint Ventures with manufacturers based in Korea and China.

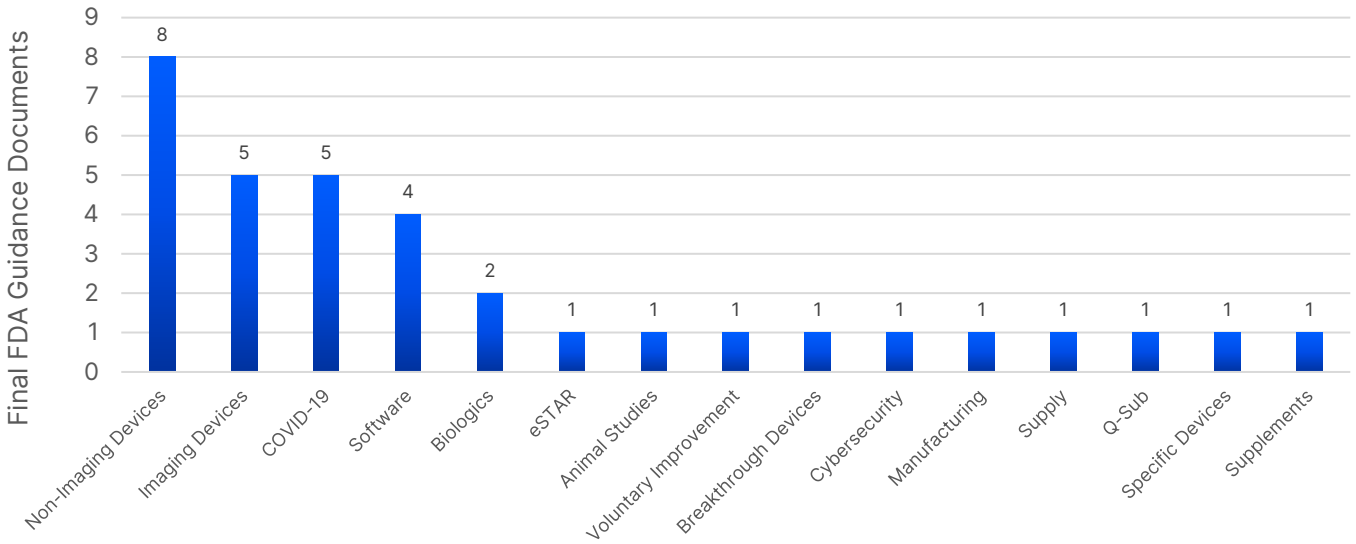
- **Regulatory Planning**: Understanding the median times to decision for different regulatory pathways can help in planning product development and launch timelines. The longer timelines for De Novo and PMA pathways necessitate earlier and more detailed regulatory engagement, but De Novo is becoming more predictable with consistent year-over-year median time to FDA decision from submission of 10 months.

- **Global Market Access**: The dominance of US-based companies in obtaining clearances and approvals implies the strategic importance of either being based in the US or having strong partnerships with US entities. For companies outside the US, this may mean considering collaborations or investments in US-based operations to leverage this advantage.

Guidance, Policies, Programs

FDA Guidance Documents for medical devices provide manufacturers with clear regulatory frameworks, ensuring safety and efficacy of devices. They facilitate innovation by outlining standards for approval, helping to navigate premarket requirements and post market surveillance efficiently. In 2023, the FDA finalized 34 Guidance Documents and issued 14 new Draft Guidance documents, giving insight into the prioritized needs and clarifications for both Industry and FDA alike.

Exhibit 10: Final FDA Guidance Documents (by Topic) issued 2023



From a final guidance perspective, two main categories of guidance documents stood out leaning towards pre-market guidance on the 510(k) pathways for specific devices across digital health and diagnostics.

(1) Guidance for COVID-19

- **Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency:** Provides temporary guidelines for the manufacture, distribution, and use of face masks and coverings, easing regulatory requirements to increase availability during the public health emergency.

- **Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19):** Outlines the process for transitioning devices that received EUA during the COVID-19 pandemic back to regular FDA oversight and approval processes as the public health emergency subsides

- **Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised):** Offers guidance on how test developers should evaluate and report the impact of viral genetic mutations on the performance of COVID-19 diagnostic tests to ensure continued accuracy and reliability

(2) Premarket Guidance for Digital Health:

- **Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions**: This document addresses the use of computational models and simulations in the premarket submission process, emphasizing their credibility and reliability.

- **Cybersecurity in Medical Devices**: Focuses on the importance of cybersecurity measures in the development and maintenance of medical devices, reflecting the increasing concern over digital security in healthcare technology.

- **Off-The-Shelf Software Use in Medical Devices**: Discusses guidelines or considerations for incorporating off-the-shelf software components into medical devices, which could involve aspects of compatibility, security, and regulatory compliance.

(3) Premarket Guidance for Imaging and Radiology Technologies:

- **Submission of 510(k)s for Solid State X-ray Imaging Devices**: Provides guidance on the submission process for 510(k) premarket notifications specifically for solid-state X-ray imaging devices, highlighting the regulatory pathway for this technology.

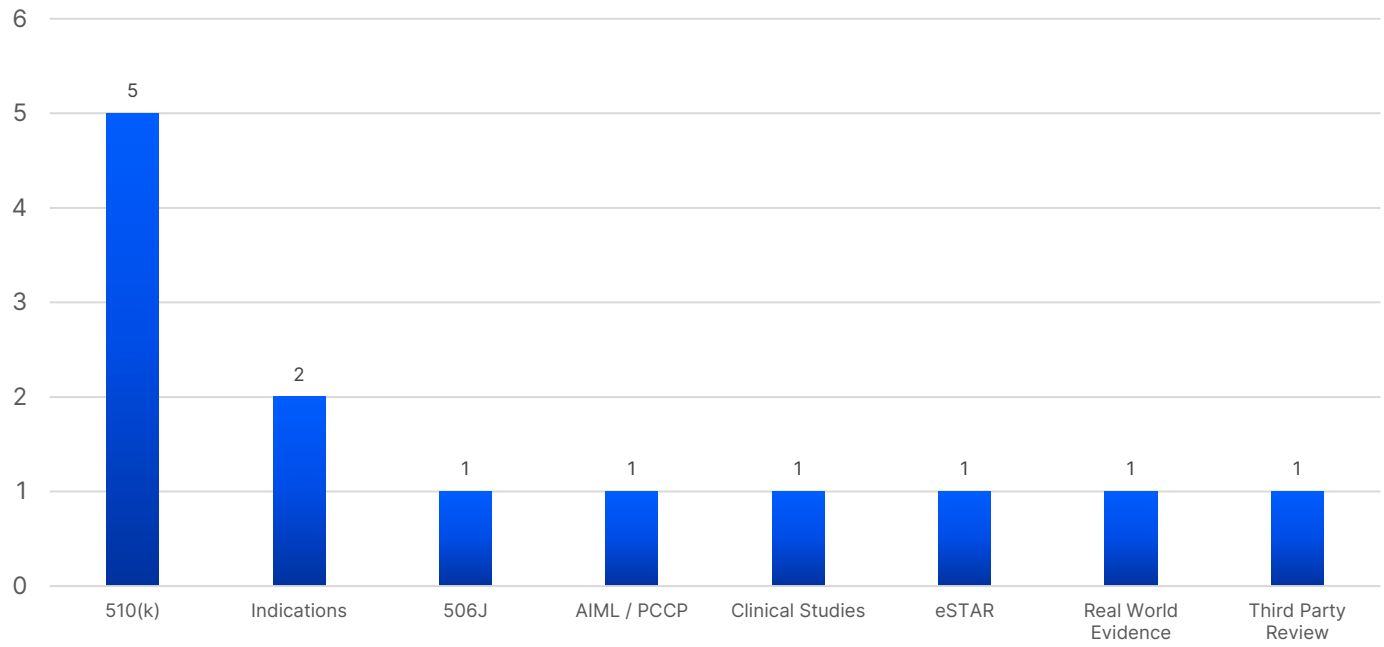
- **Marketing Clearance of Diagnostic Ultrasound Systems and Transducers**: This document outlines the requirements and process for obtaining marketing clearance for ultrasound systems and their components, indicating a focus on ensuring the safety and effectiveness of these diagnostic tools.

- **Medical X-Ray Imaging Devices Conformance with IEC Standards**: Discusses the alignment of medical X-ray imaging devices with International Electrotechnical Commission (IEC) standards, emphasizing the importance of international standards in ensuring device quality and safety.

These titles suggest a strong focus on integrating and regulating digital technologies within medical devices, highlighting areas such as cybersecurity, the use of software, and the application of computational modeling. There is also a clear emphasis on specific technologies like X-ray and ultrasound imaging devices, reflecting ongoing efforts to ensure these technologies meet regulatory standards and provide safe, effective diagnostic capabilities. These patterns indicate the FDA's commitment to adapting regulatory frameworks to accommodate technological advancements, ensure device safety and effectiveness, and address the evolving landscape of medical device development and digital health

Exhibit 11: Draft FDA Guidance Documents (by Topic) issued in 2023

For MedTech companies and the medical device industry, draft guidance documents are a key resource for strategic planning, offering insights into regulatory trends, compliance expectations, and emerging areas of interest. Engaging with these documents can help companies navigate the regulatory landscape more effectively, ensuring their products meet the FDA's safety and efficacy standards while also capitalizing on new market opportunities.



In 2023, the bulk of draft guidance documents pertain to premarket activities (e.g., six documents focused on the 510(k) process for specific devices or the eSTAR interactive PDF). Some strategic insights we can gather from these guidance documents are:

1. **Digital Health and Real-World Evidence**:
   The inclusion of topics related to digital health and real-world evidence (RWD/RWE) points to the FDA's growing interest in digital technologies and data-driven approaches to device approval and monitoring, signaling strategic areas for investment and development by MedTech companies.

2. **Emphasis on Premarket Guidance**:
   The focus on premarket and 510(k) submissions underscores the FDA's aim to provide clarity and support for companies navigating the approval process, highlighting the importance of understanding, and complying with submission requirements.

3. **Specialized Device Focus**:
   Guidance targeting specific medical specialties, like Gastroenterology-Urology, suggests that companies in niche areas may face new or updated regulatory expectations, emphasizing the need for specialization and expertise in product development and regulatory strategy.

4. **Administrative Clarity**:
   The attention to administrative and procedural aspects indicates a regulatory environment seeking to reduce ambiguity and potentially streamline approval processes, offering an opportunity for companies to engage with the FDA to understand and influence emerging regulations.

Strategic Implications of Draft Guidance

Draft FDA guidance documents signal upcoming regulatory priorities, offering Medtech companies' early insight to align product development and compliance strategies with future approval requirements and market access conditions. Below are some of the ways to practically think about how these draft guidance's impact your business looking ahead in 2024.

- **Regulatory Forecasting**: Draft guidance documents offer a preview of future regulatory directions and priorities. For MedTech companies, staying abreast of these drafts is crucial for anticipating changes that could affect product development and market strategies.
- **Opportunity for Feedback**: The draft status of these documents means the FDA is soliciting feedback from industry stakeholders. This provides a valuable opportunity for MedTech companies to influence final guidance through comments and suggestions, potentially shaping regulations in a way that considers industry challenges and innovation.
- **Innovation and Compliance Alignment**:
  Trends and subjects highlighted in draft guidance documents can signal areas of regulatory focus, such as digital health, AI in medical devices, or specific safety concerns. Medtech companies can align their innovation and compliance strategies, accordingly, ensuring that new products not only meet current standards but are also prepared for future regulatory expectations.
- **Strategic Planning**: Identifying patterns in draft guidance documents allows companies to prioritize R&D and compliance efforts. For instance, an increase in guidance documents related to digital health could signal a strategic push towards telemedicine and connected devices, prompting companies to invest in these areas. One example of an observed pattern is image analysis technology.

Conclusion

The MedTech landscape in 2024 promises to be both challenging and ripe with opportunity. As we reflect on the insights from this year's report, the industry stands on the cusp of significant transformation, driven by the rapid evolution of technology and regulatory environments. The integration of digital health solutions, artificial intelligence, and machine learning is not just a trend but a fundamental shift in how we approach healthcare innovation and delivery. We urge MedTech leaders to embrace these changes proactively, by investing in innovative technologies, adapting to regulatory evolutions, and prioritizing cybersecurity to protect patient and provider data.

Furthermore, the transition from traditional regulatory pathways to more streamlined processes, such as the FDA's eSTAR template and process and the Breakthrough Device Designation pathway, as well as more clarity in requirements around digital technologies and growing categories of medical devices such as observed with imaging and Software as Medical Devices and AI/ML-enabled devices in 2023, offers a unique opportunity for companies to accelerate the delivery of life-saving technologies to the market. However, this requires a strategic approach and commitment to regulatory excellence, with a focus on well-informed regulatory and product strategy, cross-functional collaboration, centralized communication, early and ongoing engagement with regulatory bodies, and a commitment to rigorous clinical evidence generation for obtaining positive FDA decision, generating real-world evidence, obtaining reimbursement, and enabling market adoption.

As we look ahead, the MedTech industry must also navigate the complexities of decentralized clinical trials and leverage real-world evidence more effectively, ensuring that innovations not only achieve regulatory approval but also meet the real-world needs of patients and healthcare providers.

The conclusion provided offers a comprehensive view of the future of the MedTech landscape in 2024, highlighting the transition towards more advanced digital health solutions and the impact of regulatory changes. However, one potential gap in this conclusion could be the lack of specific mention of patient engagement and participation in this transformative journey. While it discusses the industry's need to meet the real-world needs of patients and healthcare providers, it does not address how patients themselves could be more directly involved in the innovation process, nor does it address how these technological advancements could enhance the patient experience.

Another gap might be the absence of a discussion on ethical considerations, particularly in relation to AI and machine learning. As these technologies play a larger role in healthcare, ethical questions around bias, transparency, and accountability become increasingly important.

Lastly, while this report emphasizes the need for MedTech leaders to stay informed and engaged in the ongoing changes and needs for Medtech regulation, it could further stress the importance of collaboration with policymakers, insurers, and other stakeholders in the healthcare ecosystem to ensure that technological advancements are accessible and lead to equitable healthcare outcomes.

The future of MedTech is bright, but it demands resilience, adaptability, and a forward-thinking mindset from its leaders, especially in digital age of MedTech when technological advancements such as Cloud, Artificial Intelligence, and Generative AI offer the promise of accelerating time to market and revenue, of optimizing resources, reducing costs, and improving employee work life and well-being. By staying informed, engaged, and committed to regulatory excellence, MedTech companies can navigate the uncertainties of 2024 and beyond, transforming challenges into opportunities for growth and innovation.

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