CDRH Annual Report 2025

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

Contents

A Message from the **Center Director**

At CDRH, we are a person-focused organization. Everything we do begins and ends with people – the individuals living with health conditions, the providers seeking options to help their patients, and the colleagues across our Center whose dedication ensures patients and caregivers have the medical devices they need to improve their lives. Every review we conduct, every meeting we host, and every innovation we support, is rooted in our commitment to public health and the people we serve every day.

Anchored on the pillars of safety and innovation, this year's annual report highlights CDRH's resilience and sustained performance. In 2025, CDRH authorized 124 novel medical devices, including the first blood test to diagnose Alzheimer's disease – one of the highest annual totals in the Center's more than 40-year history. We strengthened safety and quality through initiatives like the Early Alert Program, which accelerates communication about potential high-risk device recalls. We convened a Digital Health Advisory Committee focused on generative-AI enabled digital mental health medical devices, reflecting our commitment to supporting responsible innovation in emerging technologies. In collaboration with the Centers for Medicare and Medicaid Services (CMS) Innovation Center (CMMI), we also announced the Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot, a voluntary pilot designed to promote access to certain digital health devices while safeguarding patient safety. We continued our focus on performance and kicked off negotiations for MDUFA VI, laying the groundwork for a modernized, predictable and efficient medical device review program that benefits patients, innovators, and the public health.

I am sincerely grateful for the incredible work of our CDRH staff. Their hard work, dedication, and unwavering focus on patients are what make this Center exceptional. This year brought several changes that required us to adjust our pace and focus our efforts. We have been thoughtful in prioritizing the work with the greatest impact on patients and public health. While some of our numbers look different than in past years, they reflect the choices we made to support CDRH staff and position the Center for long-term success. We are deeply proud of our achievements and energized by all there is to come.

Warmly,
Michelle Tarver, M.D., Ph.D.
Director, Center for Devices and Radiological Health

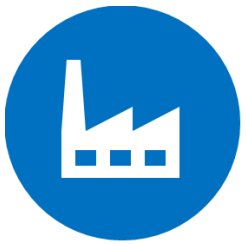
2025 CDRH Impact

CDRH's mission is to protect and promote public health while supporting timely access to innovative, safe, and effective medical devices and safe radiation-emitting products. This includes evaluating devices with innovative medical technologies, supporting manufacturers in delivering high-quality devices, and advancing safety through rigorous oversight. Every number in this report represents our commitment to improving the lives of patients, families, and communities across the country. These metrics are more than statistics – they reflect the trust placed in us, the dedication of our tireless staff, and the collective impact we achieve alongside patients, clinicians, innovators, and partners.

Together, we are shaping a health care ecosystem where technology serves people, and where every decision contributes to better health outcomes for all. Here is a snapshot of our impact in 2025.

Regulated **264,670** medical devices

Received **21,780** medical device submissions



Oversaw **25,530** registered device manufacturing firms

Reduced regulatory burden via **10** actions

Authorized **124** novel medical devices

Issued **21** guidances

Protected patients via **125** safety-related communications

Prioritizing Patient Engagement

Patients are at the heart of everything CDRH does, and their perspectives guide our day-to-day regulatory decision-making. CDRH helps to ensure that the voices of those who use medical devices inform evidence generation and innovation, while keeping patient safety and well-being at the center of all regulatory activities. This year, we strengthened opportunities for patients and caregivers to share their experiences, expanded the use of patient-reported outcomes in device authorizations, and deepened collaboration with patient communities.

We continued our work with 17 Collaborative Communities, including new participation in the Robotics, Telesurgery, and Surgical AI collaborative community. Over half of these collaborative communities include actively participating patients or patient organizations to address shared health care challenges and help ensure that medical devices are meaningfully responsive to patient needs. Additionally, CDRH held three stakeholder consultation meetings with patient and consumer advocacy groups as part of the MDUFA VI negotiations with the regulated industry.

11 ongoing patient-centered research projects with **38** publications to date and **8** clinical outcome assessments qualified as medical device development tools (MDDTs)

21 patient organizations available to further enable patient collaboration, with **6** added in 2025 specifically to support TAP innovators

54% of medical device Premarket approvals (PMAs) with Patient-Reported Outcomes (PROs)

Patient townhall on the experience of older adults in medical device clinical studies

Fostering Innovation

Innovation in medical technology is strongest when it is built through collaboration. At CDRH, we have continued to work closely with innovators, clinicians, and patients to support ideas that can meaningfully improve health and expand access to care. Through programs like the Total Product Life Cycle Advisory Program (TAP) Pilot, we provide early, strategic guidance that helps developers navigate scientific and regulatory challenges with greater clarity. Our Home as a Health Care Hub initiative furthers this work by encouraging the development of technologies that bring high quality care into the home, supporting access to health care and new models of care delivery. The Digital Health Center of Excellence (DHCoE) provides specialized expertise and resources to advance health care by fostering the responsible innovation of safe, effective, and high-quality digital health devices. Through the Breakthrough Devices Program, we work with developers of technologies that address unmet medical needs, helping to accelerate access to first-of-its-kind solutions. We also continue to advance the use of new digital tools, like Elsa, a generative AI tool, to help staff streamline routine tasks. Together, these efforts strengthen a culture of innovation that is proactive, patient-centered, and focused on delivering real impact.

> "Use of the Home as a Health Care Hub and IdeaLab tools taught us that health innovation isn't just about devices – it's about how care fits into daily life, relationships, and the spaces people call home.
>
> *–Stakeholder*

> "[TAP] has helped us increase the possibility that this technology will be adopted by clinicians. That is really important; otherwise we're risking our investment in very expensive clinical studies.
>
> *–Stakeholder*

Fostering Innovation

In 2025, CDRH continued to take steps to foster innovation through programs that support emerging technologies and advance medical device development:

Digital Health Center of Excellence

DHCoE advanced safe and effective digital health innovation by supporting CDRH reviews of medical devices, convening the Digital Health Advisory Committee, issuing a draft guidance on AI lifecycle management and marketing, launching the Regulatory Accelerator, and announcing the "Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot."

1,300+ Authorized AI-enabled medical devices to date

Breakthrough Devices Program

In 2025, 44 designated breakthrough devices received marketing authorization, including the first blood test to diagnose Alzheimer's disease and the first eyeglass lenses to slow the progression of pediatric myopia.

149 Devices designated as Breakthrough in 2025

Total Product Life Cycle Advisory Program (TAP) Pilot

TAP innovators reported a 98% satisfaction rate with FDA interactions as published in the TAP Final Assessment Report.

108 Devices enrolled in the TAP Pilot to date

Advancing Safety and Quality

Ensuring the safety, quality, and reliability of medical devices remain central to CDRH's mission. In 2025, we enrolled 10 submissions into the Safer Technologies Program (STeP) and 4 received marketing authorization, accelerating patient access to safer medical technologies. We strengthened our oversight by advancing cybersecurity readiness across the medical device ecosystem, promoting more robust protections for patients and health care systems. Through our Early Alert Pilot, we accelerated communication of potentially high-risk device recalls, enabling increased transparency and enhancing patient safety. We also continued efforts to mitigate supply chain disruptions by supporting manufacturers in maintaining continuity, resilience, and device availability during times of strain. Our focus on data integrity reinforced the foundation of trustworthy evidence in device development, evaluation, and surveillance. We convened an advisory committee meeting on issues related to emerging technology in the context of medical devices and germicidal ultraviolet (UV) light as a mode of disinfection. CDRH also successfully completed the ISO 9001:2015 surveillance audit, demonstrating that our quality management systems maintain international standards for efficiency, consistency, and continuous improvement. These initiatives demonstrate CDRH's proactive approach to protecting patients, maintaining trust in medical technologies, and ensuring that quality and safety remain at the forefront of every medical device.

Early Alert Pilot

CDRH expanded Early Alert communications to all device types to enhance early communication of potential high-risk recalls.

Cybersecurity

CDRH advanced device security by publishing a final guidance with recommendations to strengthen cybersecurity in medical device design.

Menstrual Product Safety

CDRH conducted independent research confirming that metals contained in tampons do not pose a health risk. CDRH also released draft guidance with updated labeling recommendations to provide clearer information to consumers.

Shortages Prevention

CDRH received 51 shortage notifications, 14 of which required FDA action and were successfully mitigated to reduce patient impact.

Enhancing Regulatory Impact

CDRH continues to advance regulatory science by advancing methods for using Real-World Data (RWD), innovative Regulatory Science Tools (RSTs), and qualified Medical Device Development Tools (MDDTs), which can be leveraged in medical device submissions. By optimizing the use of RWD from electronic health records, registries, and patient-generated data, we can make more informed, timely decisions that reflect real-world patient experiences. Our RSTs, ranging from predictive models to digital health evaluation methods, support the development and assessment of new technologies with greater efficiency and rigor. Through active collaboration with our international partners, including regulators and scientific networks, we have shared best practices, continued to harmonize approaches, and celebrated successful joint initiatives that accelerate global access to safe and effective medical devices. For example, the draft International Medical Device Regulators Forum (IMDRF) document Playbook for Medical Device Regulatory Reliance Programs proposed practices and examples for global regulatory authorities that may wish to leverage regulatory decisions from other regions. These efforts underscore CDRH's commitment to modern, adaptable regulatory methods that balance innovation, patient safety, and global collaboration.

Real World Evidence

More than 250 devices have been authorized using RWE to date, and CDRH is standing up an active surveillance program that monitors safety across 20 million lives. CDRH also published final guidance to support the appropriate use of RWE in regulatory decision making.

International Affairs

CDRH strengthened global collaboration through multilateral engagement in the International Medical Device Regulators Forum and the Medical Device Single Audit Program (MDSAP), helping to expand IMDRF membership to 7 new regions, adding another country to MDSAP, and contributing to new IMDRF documents in areas such as good machine learning practices.

Regulatory Tools

CDRH advanced regulatory science by qualifying 1 new medical device development tool and making available over 100 regulatory science tools in 2025, including the Chemicals List for Analytical Performance (CLAP) tool, which helps chemistry labs define the performance of their analytical methods.

Continuing High Performance

CDRH's commitment to timely, predictable, and high-quality regulatory review is reflected in our MDUFA V performance metrics. In 2025, despite resource challenges, we were on track to meet key targets for review timelines across device types, ensuring that innovators receive clear and consistent feedback while patients gain timely access to safe and effective medical devices. CDRH strengthened the MDUFA program by publishing an independent assessment of workforce capacity and updating the MDUFA V 5-year financial plan. We also continued to prioritize customer service, providing responsive guidance and support to industry, clinicians, and patients. Complementing these efforts, CDRH held our initial MDUFA VI public meeting and embarked on MDUFA VI negotiations, including six industry discussion meetings and three stakeholder consultation meetings in 2025. We have made significant headway and look forward to continued collaboration with our industry colleagues as negotiations advance.

Submission Type	Action	Review Goal	Review Time Goal	FY25 Current Performance
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	Substantive Interaction	95%	90 calendar days	✓ On Track
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	Decision (w/o advisory input)	90%	180 FDA days	✓ On Track
180-Day PMA Supplements	Substantive Interaction	95%	90 calendar days	✓ On Track
180-Day PMA Supplements	Decision	95%	180 FDA days	✓ On Track
Real-Time PMA Supplements	Decision	95%	90 FDA days	✓ On Track
De Novo Classification Requests	Decision	70-90%	150 FDA days	✓ On Track
510(k) Premarket Notification	Substantive Interaction	95%	60 calendar days	✓ On Track
510(k) Premarket Notification	Decision	95%	90 FDA days	✓ On Track
Pre-submissions	Written Feedback	75-90%	70 calendar days (or 5 days before meeting)	✓ On Track

"CDRH's collaborative approach, clear communication and prompt responses have been instrumental in guiding device development."

–Stakeholder

CDRH in Action

See how CDRH advanced public health in 2025 through FDA press announcements:

- FDA Launches TEMPO: A First-of-Its-Kind Digital Health Pilot to Expand Access to Chronic Disease Technologies
- FDA Authorizes Marketing of First Eyeglass Lenses to Slow Progression of Pediatric Myopia
- FDA Takes Action to Address Data Integrity Concerns with Two Chinese Third-Party Testing Firms
- FDA Clears First Blood Test Used in Diagnosing Alzheimer's Disease
- FDA Grants Marketing Authorization of First Home Test for Chlamydia, Gonorrhea and Trichomoniasis
- FDA Direct: An Eye on CDRH: Regulating for a New Era of Medical Devices

We appreciate the collaboration and trust of the communities we serve as we work to protect and promote public health.

Looking Ahead to 2026

CDRH is focused on fostering innovation, protecting patients, and promoting public health. In 2026, we intend to:

- Implement the new Quality Management System Regulation (QMSR) to further strengthen manufacturing quality standards across the industry;
- Promote AI, digital health, and next generation technologies;
- Expand postmarket safety efforts, sustain premarket momentum, optimize compliance activities; and
- Strengthen CDRH resilience to adapt to staffing changes, evolving processes, and shifting technological demands.

In OneCDRH fashion of advancing regulatory excellence through a proven Total Product Life Cycle (TPLC) approach to device safety and innovation, we aim to continue to align our processes with the needs of patients, industry, and the broader health care system.

Contact CDRH

Web: Center for Devices and Radiological Health | FDA

Follow CDRH

X: @FDADeviceInfo
Facebook: @FDA
LinkedIn: FDA LinkedIn

Division of Industry and Consumer Education (DICE)

Phone: 1(800) 638-2041 or (301) 796-7100
Email: DICE@fda.hhs.gov