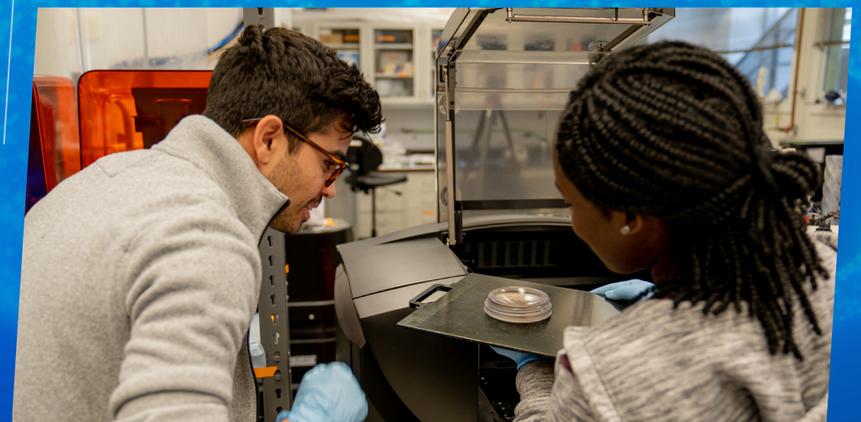


2023

Annual Report

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. FOOD & DRUG ADMINISTRATION

Contents

Center Director's Message

> This was a banner year for the Center, authorizing the highest number of novel devices on record (excluding EUAs) in CDRH's more than 40-year history.

2023 was a transformative year at the FDA's Center for Devices and Radiological Health (CDRH). We officially turned a corner on the COVID-19 pandemic and moved toward a more sustainable workload, including prioritizing normal review timelines for all incoming premarket submissions.

Since the COVID-19 Public Health Emergency (PHE) declared under the Public Health Service Act ended in May, over 40 devices have transitioned from emergency use authorization (EUA) to traditional marketing authorizations, including the first over-the-counter COVID-19 antigen test, and we continue to proactively work with sponsors to help ensure a smooth transition.

Our commitment to fostering innovation in the medical device industry and bringing important new technologies to patients remained strong in 2023, as we continued to see high numbers of novel medical device authorizations. In fact, this was a banner year for the Center, authorizing the highest number of novel devices on record (excluding EUAs) in CDRH's more than 40-year history. One example includes our clearance of the first over-the-counter fentanyl test, which the agency cleared in just 16 days – a testament to our work to further advance bringing health care into the home setting.

We also launched and then expanded the Total Product Life Cycle Advisory Program (TAP) Pilot, a key component of the latest reauthorization of the Medical Device User Fee Amendments (MDUFA) V. TAP is already working to foster innovation across the medical device industry by improving the predictability and reducing the time and cost of the "valley of death" from concept to commercialization. We believe this pilot has the potential to ultimately improve patient access to safe, high-quality, transformative, and even life-saving medical devices and spur greater investment in innovative device development, while staying aligned with the FDA's rigorous standards for device safety and effectiveness.

Ensuring technology is designed and targeted to meet the needs of diverse populations has been at the forefront of our mission at CDRH and our initiative to advance health equity. Over the past year, we expanded our Breakthrough Devices Program to include innovative technologies that help bridge this divide and helped advance technologies that meet the needs of diverse populations. This includes technology involving artificial intelligence and machine learning-enabled (AI/ML) medical devices.

In addition to fostering innovation in this ever-evolving landscape, we are also committed to ensuring patient safety and mitigating risks from potential cybersecurity vulnerabilities that have become increasingly common as more devices rely on online networks. We recently celebrated our 10-year anniversary of CDRH's Cybersecurity Program and the important work our dedicated, growing staff has done to protect patients from cyber threats to medical devices and to support U.S. government efforts to protect our national security overall. This includes implementing important new authorities the FDA received from Congress in the FY2023 Omnibus legislation (i.e., the Consolidated Appropriations Act, 2023).

While our mission remains focused on assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products, we recognize that this vital work would not be possible without engaged and knowledgeable employees that reflect the diversity of the American people we serve. That's why we have prioritized diversity, equity, inclusion, and belonging in our hiring practices, as well as enhanced employee engagement and wellness programs as a part of our 2022-2025 Strategic Priorities. We are committed to ensuring CDRH maintains a healthy, talented, and diverse workforce best fit to serve and to protect the public health.

As we look ahead to 2024, we remain committed to ensuring that CDRH is well-prepared to help the medical device industry advance new innovations in technology, as well as to address unanticipated public health challenges, while continuing to keep the public health and the people we serve at the core of our mission.

JEFF SHUREN, M.D., J.D.,
Director, Center for Devices and Radiological Health

CDRH By the Numbers

2,230 Dedicated CDRHers

257,400 Different types of regulated devices listed

21,500 Registered device manufacturing firms

19,100 Submissions received

71 New and updated guidances

CDRH Safety-Related Communications

14	Safety communications
3	Public meetings
71	Facebook posts
14	Letters to health care providers
6	Advisory Committee meetings
207	LinkedIn posts
59	Class I recall amplifications
553	External emails
536	X posts

Device Innovation

15	STeP requests enrolled
29	Submissions designated as Breakthrough Devices received marketing authorization
124	Novel devices received marketing authorization
167	Submissions designated as Breakthrough Devices

21 Total number of devices that transitioned from EUA to traditional marketing authorization

Joined **3** Collaborative Communities

★★★★★★★★★★

90% Customer Service Rating

Medical Device User Fee Amendments (MDUFA) V

CDRH worked diligently throughout 2023 to meet our MDUFA V commitments to help advance innovation and increase patients' and providers' access to safe, effective, and high-quality medical devices.

The MDUFA V agreement includes a range of review goals across the Center's various premarket programs, including more robust review goals for CDRH's handling of pre-submission requests. FY2023 saw the highest volume of MDUFA premarket submissions in at least a decade. However, even in the presence of this increased workload, CDRH is on track to meet its FY2023 review goals.

The MDUFA V agreement also includes a wide array of process improvements for activities including patient science and engagement, international regulatory harmonization, third-party review, and programmatic guidance development.

In January 2023, we launched the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot to allow for earlier and more frequent interactions with industry, more strategic input from stakeholders, and proactive, strategic advice from CDRH, to spur more investment in and rapid development of high-quality, safe, effective, and innovative medical devices that are critical to the public health. Since the program's inception, we have enrolled 15 Breakthrough-designated devices from the Office of Cardiovascular Devices (OHT2). Before the close of 2023, we expanded TAP to include devices reviewed in the Office of Neurological and Physical Medicine Devices (OHT5), which now includes 10 enrolled Breakthrough-designated devices. In 2024, we plan to enroll up to 60 devices from OHT2 and OHT5.

2023 Highlights:

Exceeded by 20% our pre-submission goal of providing written feedback to an applicant within 70 calendar days or five days prior to a meeting 75% of the time.

Required 510(k) submissions to use the Electronic Submissions Template (eSTAR).

Expanded the submission progress tracking system in the CDRH Portal. In addition to Traditional, Special, and Abbreviated 510(k)s, now users can also track online the status of their pre-submissions.

Updated guidance on Deficiency Letters and providing training to FDA review staff.

Transitioned the Accreditation Scheme for Conformity Assessment (ASCA) pilot to a permanent program.

Issued the International Harmonization Draft Strategic Plan.

Filled 100 percent of CDRH's 141 MDUFA V positions for FY2023. We are also on track to meet the FY2024 MDUFA V hiring goal.

Device Shortages

The Resilient Supply Chain Program (RSCP) plays a critical role in assuring patients have access to critical life-saving and life-supporting medical devices. Established during the COVID-19 PHE, the RSCP works with manufacturers, distributors, health care providers and others to prevent and mitigate shortages and improve the resiliency of the U.S. medical device supply chain.

In 2023, the FDA:

- Continued to work with medical device stakeholders to prevent and mitigate shortages of critical devices that most often impact our most vulnerable populations (e.g., pediatrics, veterans and underserved communities).
- Maintained the public shortages list, providing stakeholders with up-to-date information about medical devices shortages and discontinuances.
- Worked to strengthen our collaboration with manufacturers and our ability to build resilient supply chains by initiating the formation of a public-private partnership with device manufacturers and a trusted third party.
- Issued the final guidance "Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act" to assist stakeholders in the agency's implementation of Section 506J.
- Issued "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications" draft guidance to satisfy the requirements under Section 2514 of the FY2023 Omnibus. The proposed 506J device list, once finalized, will assist manufacturers in providing timely, informative notifications about changes in production of devices on the list during, or in advance of, a public health emergency.
- Led an interagency effort to convene a group of external stakeholders to deliver a report with recommendations on device types that should be included on a critical medical device list, in response to the Executive Order on a Resilient Public Health Supply Chain.

Medical device supply chains continue to be vulnerable to a wide variety of global and systemic issues, impacting multiple manufacturers and device types. CDRH's visibility into shortages caused by these issues (e.g., geopolitical, natural disasters and recalls) is limited and will remain so unless reporting authorities are expanded and the PHE temporal limitation is lifted, and the program receives full base funding to maintain its capabilities as the temporary COVID-19 funding ends. Although the FY2023 Omnibus clarified the ability of the FDA to receive voluntary notifications from manufacturers about certain device discontinuances or disruptions, recent experiences have demonstrated that relying on voluntary information-sharing deprives the FDA and the public of critical supply chain information and puts patients at risk.

Device Innovation

Upstream Innovation: Advancing Regulatory Science

CDRH's regulatory science program continues to advance upstream innovation through strategic partnerships and the provision of publicly available regulatory science tools (RSTs) for innovators, which help to streamline the path to market for safe and effective technologies.

CDRH has now made available to developers more than 150 RSTs in our online catalog of tools and we have begun tracking their use in premarket submissions. The tools provided to innovators have been used in many submissions over multiple areas of technology. For example, in one case, a single RST has been used in more than 450 premarket submissions across all eight Offices of Health Technology (OHTs). CDRH continues to expand the number of RSTs available as we move into 2024.

In 2023, our strategic partnerships with the Veterans Health Administration (VHA) and National Institutes of Health (NIH) have been significantly strengthened, with several CDRH staff now working at the VHA Research and Development facility in Seattle, WA.

Marketing Authorizations for Novel Devices

In 2023, CDRH gave marketing authorization to 124 novel devices (excluding EUAs) – the highest on record in the Center's history.

CDRH continues to see high numbers of novel devices coming to market, with an almost five-fold increase in novel device authorizations since 2009. Novel or innovative does not simply mean "new" – it also means there is a benefit to patients. Many of these devices address an unmet need or may be safer or more effective than currently available alternatives.

Novel device authorizations demonstrate the remarkable ability of stakeholders and the FDA to effectively work together to assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices.

Notable examples include:

Alltest Fentanyl Urine Test Cassette

The first over-the-counter test for the preliminary detection of fentanyl in urine.

SNOO Smart Sleeper

An over-the-counter infant sleep system intended to help infants up to six months of age who are not yet able to roll over consistently lie flat on their back during sleep.

SafetyNet Opioid System

A monitoring device intended to recognize and respond by a series of escalating notifications when an individual may be experiencing Opioid Induced Respiratory Depression (OIRD) due to opioid use or overdose.

Personal Genome Service (PGS) Genetic Health Risk Report for BRCA1/BRCA2

A direct-to-consumer (DTC) test that reports selected BRCA1/BRCA2 genetic variants from saliva collected from people 18 years of age or older.

Inspire II Upper Airway Stimulator (UAS) System

An implantable nerve stimulator that detects the patient's breathing pattern and maintains an open airway with mild stimulation of the nerves of the tongue. It was expanded for use in certain pediatric patients, between 13 and 18 years of age, with Down syndrome and severe obstructive sleep apnea.

Fluorescence Guided Gastric Calibration Tube

The first Safer Technologies Program (STeP) device authorized for marketing. It is intended for use during gastric and bariatric surgical procedures to provide fluorescence-guided visualization of the tube position, and to serve as a sizing and measurement guide during gastric resection, as well as to facilitate stomach decompression, drainage of gastric fluids, and testing for staple line leaks.

Stanza

A smartphone-based prescription digital therapeutic that provides acceptance and commitment therapy (ACT), a form of cognitive behavioral therapy (CBT). This device is indicated for the treatment of fibromyalgia symptoms in adult patients.

Owlet Dream Sock

The first over-the-counter medical pulse oximeter for infants. The Dream Sock monitors and displays Baby's Live Health Readings, including pulse rate and oxygen saturation level, and will provide Health Notifications, which will alert caregivers with lights and alarm sounds if their infant's readings fall outside of preset ranges.

Device Innovation

Expediting Premarket Submissions

This past year, our Breakthrough Devices Program continued to help increase access to innovative, high-quality medical devices by expediting their development, assessment, and review, while assuring these devices meet the FDA's statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization. The program reflects our commitment to advancing the public health by engaging with industry to help bring innovative technologies to market for patients in need.

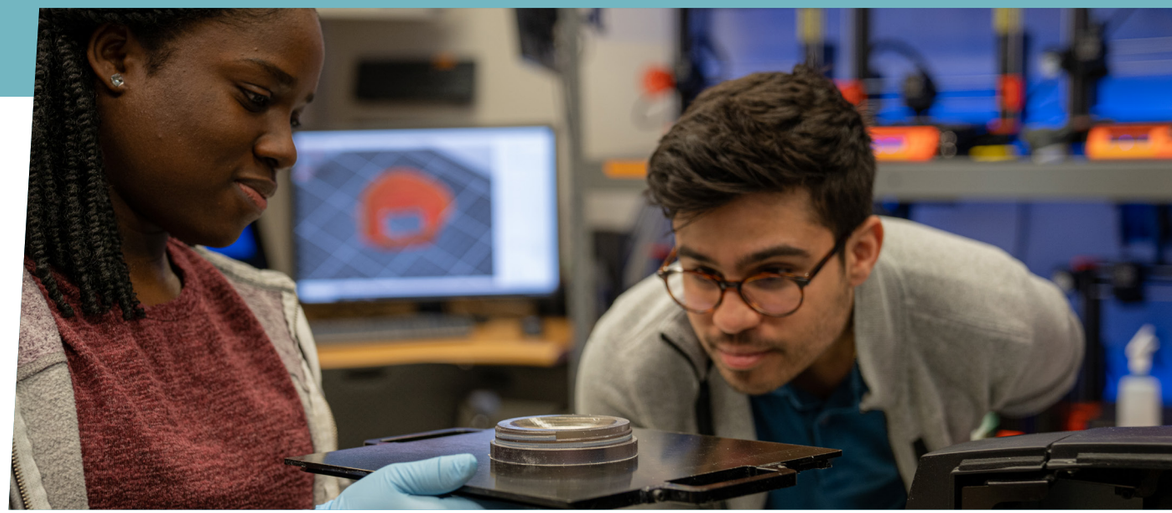
In 2023, CDRH granted Breakthrough Device designation to 167 devices and granted marketing authorization to 29 Breakthrough Devices. Since the launch of the Breakthrough Devices Program, the agency has granted Breakthrough status to 921 devices as of the end of 2023, including devices originally designated under the Expedited Access Pathway program that started in 2015.

We also issued an updated guidance that clarifies additional considerations in designating devices, including how the Breakthrough Devices Program may be applicable to certain devices that benefit populations impacted by health and/or health care disparities, as well as clarifies that the program may be available for certain non-addictive medical products to treat pain or addiction, as provided under the SUPPORT Act.

For devices that offer a significant safety improvement, but do not otherwise qualify for the Breakthrough Devices Program due to the less serious nature of the disease or condition for which they are used, the voluntary Safer Technologies Program (STeP) may be available. Similar to the Breakthrough Devices Program, STeP offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA in a timely way. There are currently 35 devices included in the STeP program, 15 of which were enrolled in 2023. Additionally, in 2023, two STeP Devices were authorized for marketing.

ISO Certification

In 2023, we also successfully expanded our ISO 9001:2015 quality management certification to include the Office of Science and Engineering Labs (OSEL) and the Office of the Center Director (OCD), in addition to the CDRH Quality Management and Organizational Excellence Program (QMOE), reinforcing our commitment to providing our stakeholders with high quality products and services.



Modernizing the 510(k) Program

The FDA recognizes there is a need to continue to enhance and adapt the 510(k) Program to best advance more modern technologies and continually improve the safety and effectiveness of medical devices under this program. In September 2023, CDRH issued three draft guidances intended to support efforts to continue to strengthen and modernize the 510(k) Program and advance the safety and effectiveness of medical devices as they become more complex and innovative. Issuing these draft guidances marked an important step in CDRH's ongoing commitment to optimize the clarity, predictability, and consistency of the 510(k) Program as we implement MDUFA V.

Device Innovation

Fostering Digital Health Innovation

In 2023, our Digital Health Center of Excellence (DHCoE) continued to foster innovation for new and emerging digital health technologies (DHTs), including AI-ML-enabled devices.

To date, CDRH has authorized over 700 AI/ML-enabled medical devices, and more are under development. The DHCoE continues receiving and responding to hundreds of inquiries each year to help stakeholders navigate policy issues and potential review requirements for new technologies.

In 2023, the DHCoE responded to more than 900 inquiries. The DHCoE also provides assistance to developers through CDRH's pre-submission program and its device determination program.

With continued innovation and rise of DHTs, the DHCoE is consistently engaged to assure a clear, predictable path to market for these technologies, while assuring patients can depend on them. This includes several noteworthy accomplishments for 2023:

Published the draft guidance Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions, which is used to further develop a regulatory approach tailored to AI/ML-enabled devices.

Released internationally the Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles with our partners from Health Canada and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA), which draws upon existing guiding principles around Good Machine Learning Practices.

Issued final guidance for Content of Premarket Submissions for Device Software Functions that ensures developers and other industry stakeholders have the information and tools they need for an efficient premarket submission process and is a key piece of our efforts to bolster digital health innovation.

Created a Digital Health Advisory Committee to solicit views from technical and scientific subject matter experts to improve the FDA's understanding of DHTs that supports safe and effective regulation while encouraging innovation.

Released two new Augmented Reality (AR) and Virtual Reality (VR) Infographics to help patients better understand and discuss with their provider the use of medical extended reality (XR), including AR and VR technology, and to assist clinicians whether to use medical XR in their practice or outside non-clinical settings such as at home.

Contributed to public-private partnerships to develop and implement AI assurance standards by fostering regulatory science research that enables FDA's experts to understand and assess benefits and risks of new DHTs.

To date, CDRH has authorized over 700 AI/ML-enabled medical devices, and more are under development.

Device Safety

CDRH Spotlight

MQSA Rule

On March 9, 2023, CDRH issued the "Final Rule to Amend the MQSA Regulations" to modernize mammography regulations under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as part of our broader commitment to improve the health of women and strengthen the fight against breast cancer.

The updated final rule incorporates current science and mammography best practices to ensure our approach to care is modernized and of the highest quality for patients. Mammograms continue to be the best tool for breast cancer screening and detection.

Under the new regulation, providers performing mammograms are required to inform patients about the density of their breasts. Roughly half of women over the age of 40 in the U.S. have dense breast tissue, which has been identified as a risk factor for developing breast cancer, and in some cases, can make cancers more difficult to detect on a mammogram. Informing patients of their breast density can help prompt additional screenings and ultimately identify whether cancer is present.

Our update also seeks to strengthen the FDA's oversight and enforcement of mammography facilities and help physicians better categorize and assess mammograms.

Device Safety

Laboratory Developed Tests: Taking Steps to Ensure Safety and Effectiveness

In October 2023, the FDA issued a proposed rule aimed at helping to ensure the safety and effectiveness of laboratory developed tests (LDTs), which are used in a growing number of health care decisions and for which the FDA's concerns have increased in recent years. In vitro diagnostic products (IVDs), including LDTs, can be used to measure or detect substances, analytes or markers in the body, such as proteins, glucose, cholesterol or DNA, to provide information about a patient's health, including to detect, monitor, or determine treatment for diseases and conditions.

The proposed rule would amend the FDA's existing regulations to make explicit that IVDs are devices under the FD&C Act, including when the manufacturer is a laboratory. The proposal also includes a phaseout of the general enforcement discretion approach for most LDTs.

The FDA has generally not enforced applicable requirements with respect to most LDTs. This is a relic of the FDA's approach from half a century ago when tests made and used in a single lab were generally simple, often made to address local individual needs, and mostly manufactured in small volumes. In the Notice of Proposed Rulemaking (NPRM), the FDA stated that the agency was proposing the rule because the risks associated with most modern LDTs are much greater now than decades ago and the current approach of not actively overseeing LDTs has created disincentives for innovation by non-laboratories. This proposed rule is an important step in the FDA's work to address LDTs.

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Device Safety

Philips Recall Response

The FDA remains steadfast in our commitment that patients impacted by the June 2021 recall of certain Philips Respironics ventilators, bilevel positive airway pressure (BiPAP) machines, and continuous positive airway pressure (CPAP) machines deserve relief. The FDA has vigorously investigated and has taken a series of actions to help support people using these affected devices. The FDA continues to take steps, including regular monitoring of Philips' reported progress on the remediation and replacement of these critical devices, to ensure patients receive accurate and transparent information about this recall.

From the start of the recall in 2021, we have mobilized a dedicated response team across the agency to work on the regulatory efforts related to this recall and to address questions and concerns raised by patients, consumers, and health care providers, who have played an integral part in providing feedback to the FDA. In 2023, we continued to actively work to hear their voice by holding listening sessions, conducting message testing focus groups, ensuring patients and providers have ongoing contact with the FDA for information about the recall, and assisting individual patients to help meet their needs.

As a part of our continued efforts to ensure patients, consumers, and health care providers have the latest information on the Philips' recall, we incorporated their feedback and developed a new resource section on FDA.gov to provide timely and accurate information. We also included a comprehensive timeline of FDA activities related to the June 2021 recall for transparency.

We understand the recalled ventilators, BiPAP machines, and CPAP machines deliver critical care and serve an important public health need for a widespread patient community. Ensuring patients and providers have the most accurate and up-to-date information about the Philips recall, and access to needed devices, remains of utmost importance to the FDA. We are committed to doing everything we can to protect the health and safety of patients affected by this recall.

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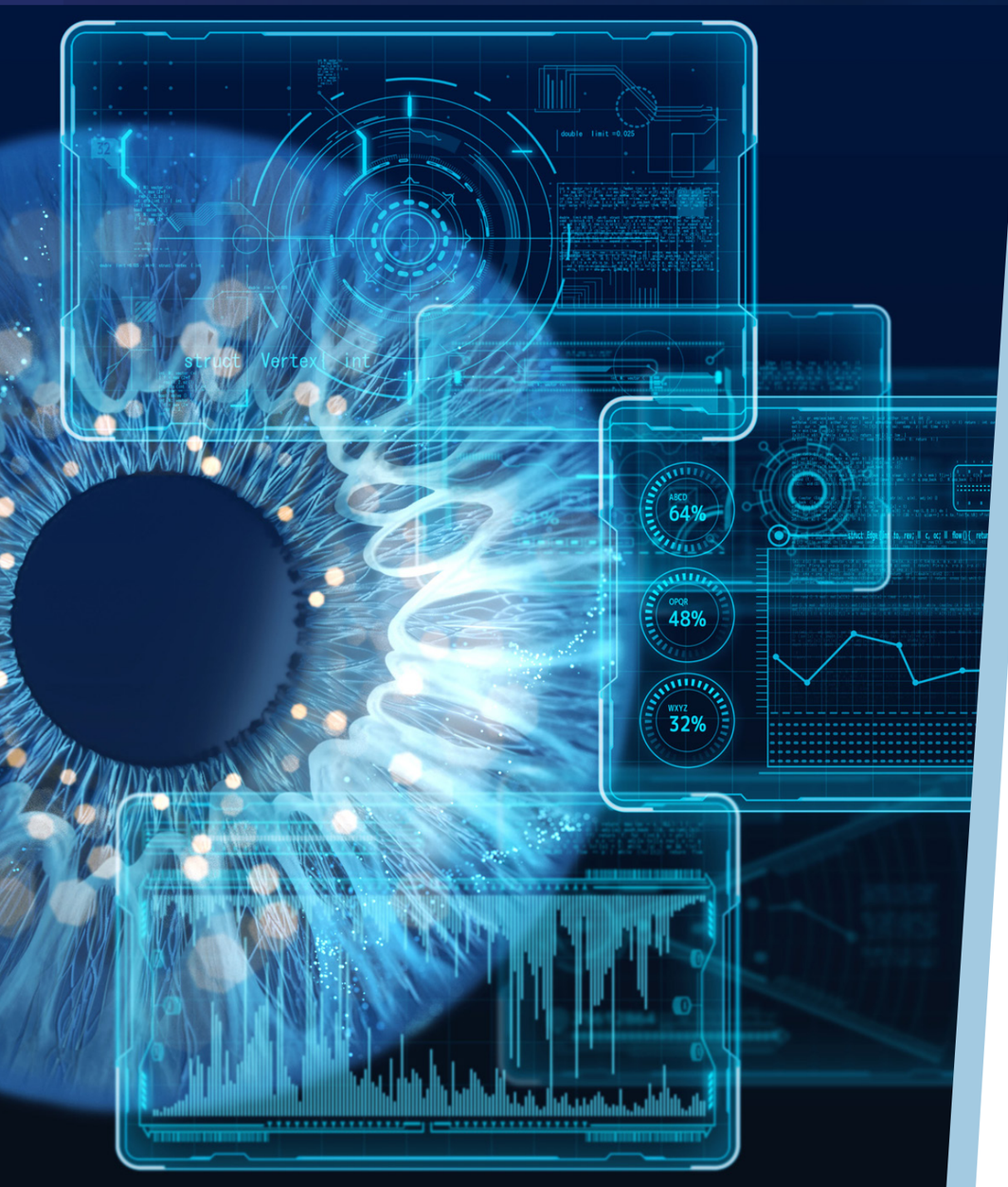
Device Safety



Preventing Harm Through Cybersecurity

2023 marked the 10-year anniversary of CDRH's robust cybersecurity program, which continues to evolve to meet the growing challenges the medical device industry faces as it becomes increasingly integrated with digital components, and therefore, more vulnerable to cyber threats and incidents. Patients, industry, other federal agencies, and all segments of the ecosystem—including health care delivery organizations and researchers—depend on this program to help assess the scope of cyber threats, coordinate mitigations, and support our entire health care system to help prevent harm to patients. The FDA has also spearheaded international medical device cybersecurity risk management efforts through the co-chairing of the International Medical Device Regulators Forum (IMDRF) Cybersecurity Working Group, which published two final guidances this year on key cybersecurity topics, building off the seminal IMDRF cybersecurity guidance published in 2020. In just the past three years, thanks to support the FDA has received from Congress, we have more than doubled the number of dedicated cybersecurity staff and set up a centralized program to ensure the issue remains a priority for the agency.

In 2023, we continued to take robust actions to ensure U.S. patients and providers have access to the most secure medical devices in the world:

On May 1, we released a comprehensive, informational video for providers to help them prepare for cybersecurity threats, and continued to serve as a vital resource throughout the year for industry and other stakeholders seeking to learn how to protect medical device infrastructure from cybersecurity vulnerabilities.

On September 27, we issued the final guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," which provides recommendations on cybersecurity considerations for devices, as well as recommendations for documentation in device premarket submissions.

With new authorities granted to the FDA under the FY2023 Omnibus, and new requirements for manufacturers that went into effect this year, we are now better positioned than ever before to ensure that the medical device industry is equipped with the tools and information it needs to prepare and address any and all cybersecurity vulnerabilities and threats.

Device Safety

Promoting International Alignment of Regulations and Standards

CDRH is committed to assuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices by engaging with international regulatory agencies to promote alignment in medical device regulations and standards. CDRH also recognizes international harmonization is an important step in reducing barriers to medical devices with the potential for important public health impact.

This year, CDRH issued the draft International Harmonization Strategic Plan to directly encourage harmonization, convergence, and reliance among medical device regulatory authorities, and build on the Center's current work with international stakeholders. As a part of MDUFA V obligations and over the next four years, we will provide updates on our work toward the strategies and activities outlined in this plan.

Looking Ahead

CDRH worked tirelessly in 2023 to continue ensuring the highest standards for medical device safety for U.S. patients. We remain committed to protecting and promoting the public health, while advancing innovative solutions to meet new and challenging issues facing the evolving medical device landscape. Our accomplishments throughout 2023 were only made possible by the dedication and expertise of our staff. We look forward to the new year and are proud to continue carrying out our commitment to serve the public health.

ADDITIONAL INFORMATION

Safety Communications: 2023 Safety Communications

Guidances: Guidance Documents (Medical Devices and Radiation-Emitting Products)

Recalls: 2023 Medical Device Recalls

Letters to Health Care Providers: 2023 Letters to Health Care Providers

Device Approvals: 2023 Device Approvals

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