Annual Report 2024

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

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A Message from the Center Director

Patients are at the heart of the work we do at the FDA's Center for Devices and Radiological Health (CDRH). As a practicing clinician and the founder of our Center's patient science and engagement program, I understand how critical the patient perspective is to the decisions we make at the FDA. That is why, as the new Center Director, I am committed to continuing to focus on the people we serve and build upon the important work the Center has accomplished.

Over the past year, I've talked with many patients from across the country, whose unique health care experiences play an important role in shaping the work we do every day. Whether it's learning about the many barriers people with diabetes face as they manage their condition, or understanding how individuals living with chronic pain weigh the benefits and risks associated with their treatment options, patients' voices are crucial to informing our regulatory decision-making and our mission to protect and promote the public health.

While 2024 was a year of transition, we remained steadfast in our commitment to ensure that all patients in the United States have access to innovative, safe, and effective medical devices and safe radiation-emitting products. We also continued to advance our core pillars of safety and innovation, as highlighted in our **2024 Safety and Innovation reports**.

As part of our commitment to further protect patients, we launched a new **communications pilot to enhance the medical device recall program**. The goal of the pilot is to increase transparency with the public and improve the timeliness of communications about corrective actions being taken by companies that the FDA believes are likely to be high-risk recalls. We also continued taking actions to address data integrity issues and substandard products, including plastic syringes made in China.

Simultaneously, our efforts to support innovation remained strong as we experienced another banner year for novel medical device authorizations. In 2024, we authorized 120 novel medical devices — among the highest annual number in our more than 40-year history — such as the **first ever device approved for automated insulin dosing** for patients with Type 2 diabetes.

We have continued to help foster innovative technologies through our **Breakthrough Devices Program** to help meet the needs of diverse populations. In addition, we worked to further promote the use of **Real-World Data (RWD) and Real-World Evidence (RWE)** in place of conventional clinical trial data to reduce the time to answer important device questions. We have authorized more than 180 devices, at least in part on the basis of RWE — with 50 in FY2024. These represent important advancements for patients who need safe and effective options to improve and extend their lives.

In October, we held a **Patient Engagement Advisory Committee (PEAC) Meeting** on Patient-Centered Informed Consent to incorporate patient feedback into policies and practices on the informed consent process in clinical studies of FDA-regulated medical products. We also hosted our inaugural **Digital Health Advisory Committee** meeting focused on generative artificial intelligence (AI) to discuss how we evaluate the benefits and risks of cutting-edge technologies.

At CDRH, we believe putting patients first means putting all patients first. In 2024, we launched **Home as a Health Care Hub** to help the medical device industry reimagine the home environment as an integral part of the health care system that can improve care delivery for all patients, including those in rural and underserved communities.

I am proud of the work we accomplished together in 2024 and look forward to continuing our efforts in the year ahead.

I want to recognize the dedicated CDRH employees who have worked tirelessly to help carry out our statutory responsibilities to protect and promote the public health with a focus on continuing to advance medical device safety and innovation. I also want to thank our former Center Director Jeff Shuren, M.D., J.D., for his more than two decades of public service at the FDA, including 15 years leading CDRH.

As we look ahead to this year and what the future holds, we will continue to keep the people we serve at the core of our mission.

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

2024 CDRH By the Numbers

2,260 Dedicated CDRH employees

248,400 Regulated devices

24,400 Registered device manufacturing firms

20,727 Submissions received

38 Guidances published

3 Proposed and final rules issued

Safety-Related Communications

13	Safety communications
6	Public meetings and workshops
80	Facebook posts
9	Letters to health care providers
8	Advisory Committee meetings
199	LinkedIn posts
560	External emails
611	X posts

Device Innovation

17	Submissions granted into Safer Technologies Program (STeP)
42	Submissions authorizing Breakthrough designated devices
120	Novel devices received marketing authorization
156	Submissions designated as Breakthrough Devices

Joined **5** Collaborative Communities

91% Customer Service Rating

Medical Device User Fee Amendments V

Medical Device User Fee Amendments (MDUFA) V represents a substantial investment in the future of the FDA's medical device program and in the health of U.S. patients. In 2024, CDRH worked tirelessly to meet our fiscal year 2024 (FY24) MDUFA V commitments agreed upon by the FDA and the medical device industry to ensure patients have access to high-quality, safe, and effective medical devices. These commitments represent a range of review goals across the Center's various premarket programs, including pre-submission requests.

The MDUFA V agreement also provides critical resources to support important program improvements including broadened international harmonization efforts, and greater engagement with developers of innovative technologies, and ensures patient perspectives are incorporated into medical device development.

In 2024, we enhanced the **Accreditation Scheme for Conformity Assessment (ASCA) program** and conducted a public workshop on possible expansion criteria. We also published revised draft guidance documents with programmatic improvements and additional biocompatibility methods, reflecting ASCA's new status as a permanent program.

We also continued the expansion of the **Total Product Life Cycle Advisory Program (TAP) Pilot**, which aims to expedite patient access to innovative medical devices by providing device developers early, frequent, and strategic communications with the FDA. This work also helps facilitate engagement with other key parties for developers of devices of public health importance. As of December 31, 2024, there were 63 Breakthrough Devices enrolled in the program and we expect that number to increase in the coming year as we continue to enroll devices in the Office of Cardiovascular Devices (OHT2), the Office of Neurological and Physical Medicine (OHT5), the Office of Radiological Health (OHT8), and the Division of Ophthalmic Devices (DHT1A). We also plan to make devices from the Office of Orthopedic Devices (OHT6) eligible for the program in early 2025.

2024 Highlights:

- Filled 100% of CDRH's MDUFA V hiring targets for FY24 (42 hires).
- Published **MDUFA V Five-Year Financial Plan and FY24 Update**.
- Met MDUFA V deficiency goal of providing a "statement of basis" in 87% of deficiencies.
- Expanded our **Submission Progress Tracking System** in the CDRH Portal to include Premarket Authorizations (PMAs).
- Issued **draft guidance** to clarify the focus of pre-submissions.
- Held a public workshop on the use of patient-generated health data in medical device development.
- Issued **draft guidance Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle** to communicate when and what methods can be used to collect and submit patient preference information (PPI) across the total product life cycle.

International Harmonization

Chairing the International Medical Device Regulators Forum

In 2024, we were honored to chair the **International Medical Device Regulators Forum (IMDRF)**, bringing together the global medical device community to promote an efficient and effective regulatory model for medical devices that is responsive to emerging technologies and challenges, while protecting and maximizing the public health.

We hosted two of the organization's largest meetings in its history with nearly 1,200 participants both virtual and in-person at our spring session in Washington, D.C., and roughly 1,300 participants at our fall meeting in Seattle, Washington. During these sessions, device regulators and manufacturers from across the globe discussed harmonized approaches to facilitate and broaden patient access to high-quality, safe, and effective devices in the U.S. and globally.

As Chair, we prioritized expanding the membership and diversity of IMDRF by bringing in more countries.

In 2024, 15 new countries joined IMDRF as Affiliate Members and one as an Official Observer.

As additional countries join IMDRF, we will continue working toward our shared vision of positively impacting the health and quality of life for patients across the world by aligning on policies, standards, and practices.

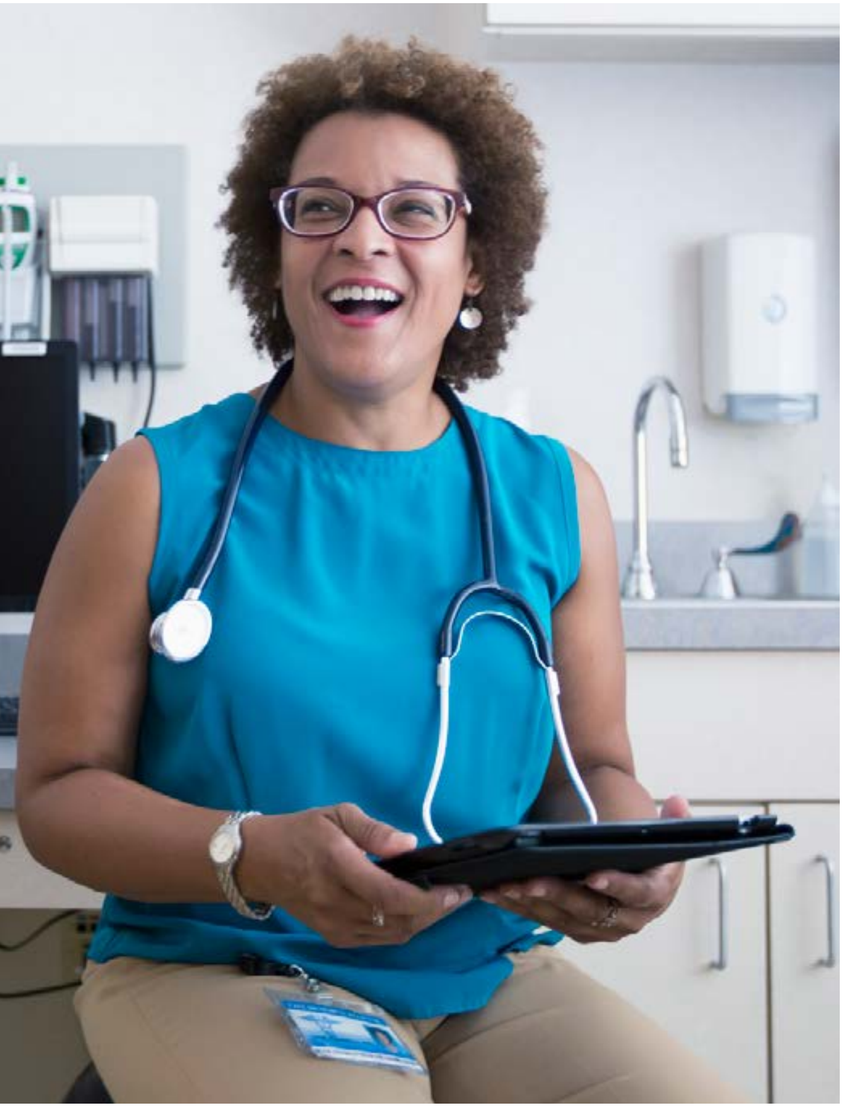
Enabling International Harmonization of Quality Management

The global medical device industry and the technologies they develop are evolving at an unprecedented pace. It is our shared responsibility to ensure these devices are fit for purpose before coming to market, they remain so once on the market, and that patients have timely access to them.

In addition to chairing IMDRF in 2024, we took the following critical steps to ensure greater harmonization and communication among the world's medical device regulators and industry:

- The IMDRF Management Committee, under the FDA's chairmanship, approved two New Work Item Proposals (NWIPs) for IMDRF working groups to develop a document outlining a technical framework for artificial intelligence life cycle management and another document on the essential principles and content of Predetermined Change Control Plans.
- In early 2024, the FDA issued a **final rule amending the Quality System regulation under 21 CFR Part 820 rule** in order to align more closely with the international consensus standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016.
- An IMDRF working group expanded the **Medical Device Single Audit Program**, which allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory jurisdictions, to 7,277 medical device manufacturers across 72 countries.

Supply Chain Resilience



Preventing and Mitigating Supply Chain Interruptions

Our **Office of Supply Chain Resilience (OSCR)** continued its crucial work to enhance the FDA's capacity to prevent and mitigate supply chain interruptions and to promote resiliency in the U.S. medical supply chain. This includes helping assure patients maintain access to devices they can depend upon in the face of widespread problems with substandard and fraudulent products from international firms, largely from China.

OSCR identifies supply chain risks and provides actionable information on those risks to industry, health care providers, patients, and government partners. We develop strategies and informational products to help prevent, and when possible, mitigate supply chain disruptions and shortages. Supply chain resilience is essential to ensuring patients in the U.S. have timely access to critical lifesaving and life-supporting medical devices and is critical for U.S. national security.

In 2024, the FDA:

- Completed the development of a publicly available **Critical Medical Device List (CMDL)**, in response to the Executive Order on a Resilient Public Health Supply Chain. The CMDL facilitates supply chain resilience through policy, regulatory, procurement, production, and inventory decisions across the medical device ecosystem, with particular emphasis on medical devices used in care delivery, clinical diagnostic assessment, clinical laboratory testing, infection control, and medical imaging.
- Led close coordination with medical device manufacturers and intra- and interagency partners to prevent and mitigate shortages of blood culture media, ventilators, and other critical devices that are needed to provide lifesaving and life-supporting treatment to all communities.
- Continued assessments of the supply chains for plastic syringes as the U.S. continued to discover problems with these and other products from China.
- Maintained the **Medical Device Shortages List,** providing industry partners, health care providers, patients, and the public with up-to-date and accurate information about medical device shortages and discontinuances.

In October 2024, back-to-back hurricanes hit the East Coast and resulted in a dramatic uptick in demand for IV bags and other devices. The impact of these natural disasters further demonstrated that medical device supply chains continue to be vulnerable and that industry, patients, health care providers, and the U.S. government depend on CDRH's OSCR to support the U.S. response. OSCR's visibility into potential shortages and supply chain issues during these situations and others is limited and will remain so unless the program receives full base funding to maintain its capabilities as the temporary funding for COVID-19 ends and the public health emergency temporal limitation is lifted.

CDRH Spotlight

In April 2024, CDRH launched **Home as a Health Care Hub**, a new initiative aimed at reimagining the home environment as an integral part of the health care system. The initiative will be a vital resource for medical device and consumer technology developers, and ultimately for patients who would benefit from access to novel devices for use in the home.

Devices for use in the home are often designed to operate in isolation rather than as part of an integrated, holistic environment. CDRH contracted with architectural firm HKS, Inc. to design a virtual reality-enabled home prototype that companies can consider when developing their devices. The prototype can be used to help identify potential barriers and improve existing products for patients with chronic conditions. It will also help identify critical features of the home that will inform how diagnostic and therapeutic devices could be better incorporated into home, school, or work environments.

CDRH chose to focus the prototype on diabetes, a chronic disease that impacts daily life. More than 38 million people in the U.S.—or nearly 12% of the U.S. population—have diabetes, according to the **Centers for Disease Control and Prevention's National Diabetes Statistics Report**.

The prototype, named Lilypad™, is housed in the **Home as a Health Care Hub's Idea Lab**, and gives users an immersive experience inside various affordable homes of representative people living with diabetes. The Idea Lab, unveiled on December 30, 2024, will also include insights from patients, caregivers, providers and experts, tours of different types of affordable housing environments, and landscape research into design opportunities ripe for innovation.

Our Home as a Health Care Hub initiative has the potential to advance health outcomes by moving care, as well as prevention and wellness, into the home setting. By taking into consideration the perspective of the health care provider, the needs of medical device companies, and most importantly the patient voice, we can enable health and wellness technologies that seamlessly integrate into people's daily lives.

Device Safety

In 2024, we continued to take significant actions to protect patients, improve device safety, and enhance our ability to identify and address new safety signals as they arise.

In 2024, CDRH issued
13 safety communications,
9 letters to health care providers,
108 recall summaries, and
44 warning letters.

We also made advances to coordinate safety communications with other major market regulators and issued a safety-related communication in coordination with Health Canada, a joint effort to simultaneously share safety information with health care providers and facilities in both countries.

Enhancing the Medical Device Recall Program

As part of our work to strengthen our medical device recall program, CDRH announced a **new communications pilot** in November 2024 aimed at improving overall timeliness of communications about corrective actions being taken by companies the FDA believes are likely to be high-risk recalls. These actions may include when companies remove products from the market, correct products, or update instructions for using products due to potentially high safety risks. This pilot includes early alerts of potentially high-risk device removals or corrections related to cardiovascular, gastrorenal, general hospital, obstetrics, gynecology, and urology. The goal of this pilot is to increase transparency and minimize the time between the FDA's initial awareness of and public communication of potentially high-risk medical device removals or corrections, providing more timely communication to health care providers and the public.

Ensuring the Safety and Integrity of Devices

CDRH remains committed to ensuring the safety of devices, including those coming to the U.S. from foreign countries, and monitoring all available sources of data for reports of problems in a timely manner.

In November 2023, **we issued a safety communication warning of potential device failures with certain plastic syringes manufactured in China**. Our ongoing evaluations confirmed that issues with the quality of certain plastic syringes made in China and their distribution in the U.S. were more widespread than originally known.

Since then, CDRH identified an emerging pattern of quality issues in Chinese-manufactured syringes. In 2024, we issued six warning letters to firms, added three Chinese firms to import alerts, and announced recalls by five different firms.

CDRH has also been focused on addressing data integrity issues in connection with data and information coming from foreign countries. In September 2024, the FDA **issued warning letters to two Chinese nonclinical testing laboratories**, citing both for laboratory oversight failures and animal care violations that raise concerns about the quality and integrity of data generated by the labs.

The warning letters followed a **February 2024 letter** alerting the medical device industry to concerns regarding data from third-party test labs used in device submissions.

CDRH is committed to working with the medical device industry to remain vigilant in protecting the public health, including being proactive about ensuring the data sponsors include in medical device submissions is truthful and accurate and that devices on the market continue to remain safe and effective.

As part of our mission to protect and promote the public health, CDRH continues working to support a more resilient domestic supply chain that will help reduce our dependence on China and other foreign sources. CDRH will remain steadfast in our continued commitment to protect patients in the U.S. and to alert the public of any threats that may arise.

Taking Steps to Ensure the Safety and Effectiveness of Laboratory Developed Tests

On May 6, 2024, the FDA published a **final rule aimed at helping to ensure the safety and effectiveness of laboratory developed tests (LDTs)**. The final rule amended the FDA's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act including when the manufacturer of the IVD is a laboratory.

Along with this amendment, the FDA finalized a policy, after reviewing a large volume of public comments, under which the agency will provide greater oversight of IVDs offered as LDTs through a phaseout of its general enforcement discretion approach for LDTs over the course of four years. The final rule also includes targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories.

We are currently working to implement the phaseout policy through the issuance of **LDT-related guidance documents, webinars, and FAQs** posted on the agency's website, and other activities.

Additionally, in June 2024, CDRH issued a guidance intended to assist small entities in complying with the requirements established in FDA regulations as they apply to IVDs, including LDTs: **Laboratory Developed Tests: Small Entity Compliance Guide**.

Device Safety

Advancing Safe, Innovative Medical Device Sterilization Efforts

The FDA is actively working with sterilization experts, medical device manufacturers, and other government agencies to advance innovative ways to sterilize medical devices with lower levels of currently used agents, and employ new agents or alternatives, while maintaining device safety and effectiveness.

In 2024, CDRH hosted a **series of 15 medical device sterilization town halls**, which focused on the agency's efforts and actions to help ensure sterilization capacity in the U.S. as well as recent activities to reduce overall reliance on ethylene oxide (EtO) while maintaining a resilient supply of sterilized medical devices.

In addition to the town hall series, we achieved a number of notable accomplishments in 2024:

- Updated the sterilization guidance, **Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile**, to include vaporized hydrogen peroxide (VHP) as an Established Category A sterilization process.
- Issued the guidance, **Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices**.
- Became a member of the new Kilmer **Collaborative Community** on Sterility Assurance.
- Stood up the CDRH Sterilization Standards Task Force.
- Added reprocessing and sterilization as a new area of interest in the **Experiential Learning Program** for CDRH employees.
- Recognized nine sterilization standards.

Protecting Medical Devices from Cybersecurity Threats

Due to rising cybersecurity threats against the health care sector, cybersecurity measures are critical to ensuring the safety and delivery of care. Patients, industry, other federal agencies, and all segments of the ecosystem — including health care delivery organizations and researchers — depend CDRH's Cybersecurity program to help assess the scope of cybersecurity threats, coordinate mitigations, and support our entire health care system to help prevent harm to patients. In 2024, we continued building upon this work and took new actions to help ensure patients and providers in the U.S. have access to the most secure medical devices in the world, including:

- Continued implementation of new authorities granted to the FDA under the **FY23 Omnibus** and support for manufacturers complying with new requirements.
- Jointly published **Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together** with the FDA's Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Office of Combination Products (OCP), in March 2024.
- Issued the draft guidance, **Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act**, in March 2024.
- Contracted for infrastructure and the building of an automated Software Bill of Materials (SBOM) and vulnerability analysis reporting tool to streamline and support FDA reviews of SBOM.
- Contracted for the analysis and best practices development for SBOM data management, which the Cybersecurity & Infrastructure Security Agency (CISA) plans to use to support interested SBOM parties across all sectors.
- Published overview of **Digital Certificate Management for Medical Devices in *Journal of Clinical Engineering***, providing health care delivery organizations and clinical engineers with an introduction to the role of digital certificates to secure and manage access to medical devices, including discussion of potential issues.
- Executed multiple memorandums of understanding to further private, government, and public partnerships with industry, including those with the Medical Device Innovation Consortium, MedISAO, CISA, and Health Information Sharing and Analysis Center (Health-ISAC).
- Developed a **partnership with the Veterans Health Administration**, the nation's largest integrated health care system, to collaborate and address complex medical device cybersecurity challenges.

Device Innovation

At CDRH, we strive to advance medical device innovation, while continuing to prioritize patient safety. From our premarket review pathways to our programs and structures aimed at advancing innovation, we continue to take steps to ensure that the U.S. remains attractive to developers launching innovative medical devices that have the potential to make a positive impact on patients' lives.

Facilitating Upstream Innovation

Our regulatory science program continued to play a vital role in our broader work to facilitate device innovation. In 2024, we formed strategic partnerships to develop analytical methods that may be used in the development of innovative devices, including **partnering with the Bill and Melinda Gates Foundation**, to create new analytical methods to help the development of breath-based diagnostic devices for disease detection in underserved populations.

We also improved our qualification program and expanded our **regulatory science tools (RST) catalog** to more than 150 RSTs, including methods, models, datasets, and clinical outcome assessments that developers can leverage as part of their device development and submission process. To date, CDRH has qualified RSTs in all of the Offices of Health Technology, which means there are RSTs in every device technology area that CDRH oversees.

The use of peer-reviewed RSTs allows innovators to efficiently navigate the design and redesign loop as they develop data and information for premarket submissions. Developers have leveraged these tools in nearly 1,400 premarket submissions across a total of 536 unique product codes, including those for drug-eluting stents, orthopedic bone plates, and the world's first seven-tesla magnetic resonance imaging scanner.

Granting Marketing Authorizations for Breakthrough and Novel Devices

In 2024, CDRH's **Breakthrough Devices Program** and **Safer Technologies Program (STeP)** also continued to play an important role in facilitating timely access to lifesaving devices by expediting their review, while ensuring these devices met the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization.

In 2024, CDRH granted Breakthrough Device designation to 156 devices and granted marketing authorization to 42 Breakthrough Devices.

Similar to the Breakthrough Devices Program, the voluntary STeP program 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 for devices that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics. Seventeen devices were enrolled in the STeP program in 2024.

Device Innovation

In 2024, CDRH granted marketing authorization to 120 novel devices, on par with last year's record-setting number of authorizations and among the highest in the history of our Center. CDRH also continues to see a steady increase in developers of novel technologies bringing their devices to the U.S. first or in parallel with other major countries, from 54.8% in 2022 to 64.9%, as of Dec 30, 2024.

Many of these novel devices address an unmet need or may be safer or more effective than currently available alternatives. This includes the **first over-the-counter (OTC) test to detect both flu and COVID-19**. Novel device authorizations demonstrate how timely and effective interactions between the FDA and sponsors can help ensure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices.

Examples of Novel Devices:

Apple Over-the-Counter Hearing Aid Software: Intended to be used with compatible versions of the Apple AirPods Pro headphones. Once installed and customized to the user's hearing needs, the Hearing Aid Feature enables compatible versions of the AirPods Pro to serve as an OTC hearing aid, intended to amplify sounds for individuals 18 years or older with perceived mild to moderate hearing impairment.

Cologuard Plus Test: A qualitative in vitro diagnostic test intended for the detection of colorectal neoplasia-associated DNA markers and for the presence of occult hemoglobin in human stool.

Dexcom Stelo Glucose Biosensor System: An integrated continuous glucose monitor (iCGM) intended for anyone 18 years or older who does not use insulin, such as individuals with diabetes treating their condition with oral medications, or those without diabetes who want to better understand how diet and exercise may impact blood sugar levels.

NOWDiagnostics First To Know Syphilis Test: The first at-home, OTC test to detect Treponema pallidum (syphilis) antibodies in human blood.

Insulet SmartAdjust technology: The first software that automatically adjusts insulin delivery to a person with type 1 and type 2 diabetes by connecting to an alternate controller-enabled insulin pump (ACE pump) and iCGM.

Samsung Electronics Co., Ltd.'s Sleep Apnea Feature: A software-only, mobile medical application intended to detect signs of moderate-to-severe obstructive sleep apnea for adults 22 years of age and older who have not been diagnosed with sleep apnea.

Sensonics, Inc.'s Eversense AP Continuous Glucose Monitoring (CGM) System: A fully implantable sensor with an anti-inflammatory drug (dexamethasone acetate) that is slowly released onto the skin to reduce inflammation at the sensor insertion site.

Sepsis ImmunoScore: The first Artificial Intelligence/Machine Learning-Based Software that identifies patients at risk for having or developing sepsis.

Device Innovation

Promoting Digital Health Innovation and Leadership on the U.S. Approach for AI in Medical Devices

The **Digital Health Center of Excellence (DHCoE)** continues to provide leadership and strategic direction on digital health policy, innovation, technology, collaborations, and literacy.

The DHCoE builds upon the FDA's long-standing mission to protect and promote public health by helping speed innovations to ensure that patients and providers have timely and continued access to safe, effective, and high-quality digital health technologies. This includes continued work to ensure there is a clear, predictable path to market for artificial intelligence and machine learning (AI/ML)-enabled devices, and that these products continue to meet the FDA's standards when they are on the market over time.

CDRH has authorized more than 1,000 AI/ML-enabled medical devices, including more than 150 in 2024, and more are under development.

Noteworthy Accomplishments in 2024 include:

- Published the **Digital Health and Artificial Intelligence Glossary**, an educational resource to help support consistent use of digital health and AI terminology by the FDA and interested parties, including industry, digital health developers, academia, health care professionals, and patients.
- Offered new educational materials to accompany the guidance document on **Digital Health Technologies for Remote Data Acquisition in Clinical Investigations**, including CDER's **Guidance Snapshot** that highlights key points in the guidance document using visuals and plain language, and a **Guidance Recap Podcast episode** that includes an interview with the FDA, discussing the background, intent, and other key recommendations of the guidance document.
- Increased outreach effectiveness by addressing the unique needs of the digital health audience through the launch of a new **Digital Health Blog**, which publishes a series of insights and perspectives from FDA experts.
- Collaborated with Health Canada and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to jointly publish **Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles**.
- Hosted the inaugural **FDA Digital Health Advisory Committee meeting** in November 2024, to discuss total product life cycle considerations for generative AI/ML-enabled medical devices.
- Issued final guidance on **Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions**.
- Continued to address hundreds of inquiries, including those prompted through use of the online **Digital Health Policy Navigator tool**.

Looking Ahead

CDRH will continue building upon our accomplishments from the past year to ensure that all patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

We remain focused on serving all patients and will continue taking steps to assure the diversity of clinical trial cohorts for medical devices.

We will also continue to take significant actions to facilitate high-quality innovation, including modernizing our premarket review process, and facilitating more dialogue between FDA advisors and manufacturers in the early stages of development.

At the same time, we will continue to improve device safety by taking further steps to assure device quality, including expanding participation in the Voluntary Improvement Program, and enhancing our medical device recall program.

CDRH's dedicated employees are driven by our mission to protect and promote the public health, and we are proud to continue carrying out our commitment to the American public in the coming year and beyond.

Additional Resources

Safety Communications: 2024 Safety Communications
Guidances: Guidance Documents (Medical Devices and Radiation-Emitting Products)
Recalls: 2024 Medical Device Recalls
Letters to Health Care Providers: 2024 Letters to Health Care Providers
Device Approvals: 2024 Device Approvals

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