

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

# 2022

## ANNUAL REPORT

FDA





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# CENTER DIRECTOR'S MESSAGE

“Despite another year of heavy workload and strained resources, CDRH's **2,011** committed staff members accomplished a wide range of priorities that continue to protect the health and well-being of the American public.”



**While much of the attention the agency received in 2021 focused on our response to the COVID-19 pandemic, 2022 was an equally demanding and unusual year.** As the Center for Devices and Radiological Health (CDRH) transitioned from full emergency operations to more programmatic stability, we were also rising to the challenges of a new public health emergency (PHE) for mpox (“monkeypox”). Although COVID-19 has been an odyssey that we are returning home from – albeit battle-scarred – we have emerged a bit wiser and more prepared for the future to ensure we are best responding to public health needs.

Despite another year of heavy workload and strained resources, CDRH's 2,011 committed staff members accomplished a wide range of priorities that continue to protect the health and well-being of the American public. This year brought unique and important issues ranging from pulse oximeters, to device cybersecurity, to artificial intelligence (AI) and machine learning (ML), to creating better access to home-use devices, and addressing ongoing device shortage and supply chain issues. We continue to respond to these challenges through the use of innovative approaches and policies, and the continuous streamlining of internal and external processes.

A core belief of the FDA is that all people should have access to quality health care and wellness. Technology, including digital health technology, should be designed and targeted to meet the needs of diverse populations, and should facilitate bringing health care and wellness to people in the home setting. This will continue to remain a high priority for CDRH in 2023 and beyond.

This year, to continue support for these initiatives, Congress reauthorized the Medical Device User Fee Amendments (MDUFA V) for the next five years. This important program provides patients and health care providers with timely and continued access to safe, effective, and high-quality medical devices. A key component of MDUFA V is the Total Product Life Cycle Advisory Program (TAP) Pilot, with the goal of improving medical device development by increasing the predictability and reducing the time from

concept to commercialization – an approach that we very strongly believe will help improve patient access to safe and innovative medical devices first in the world.

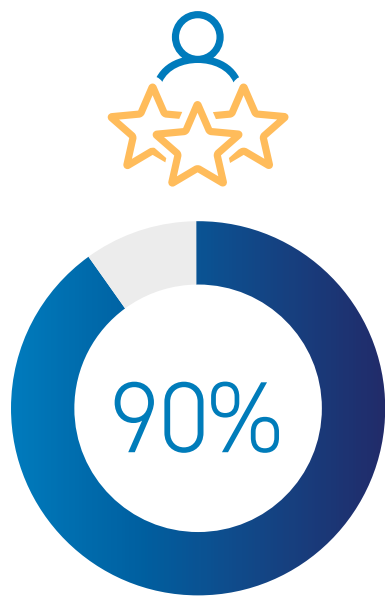
In addition to these efforts, CDRH remains charged with protecting and promoting public health and assuring the over 238,000 different types of medical devices we regulate are safe and effective for U.S. patients. We continue to monitor for and address device safety risks, such as through product recalls and safety communications, and take regulatory or enforcement action when appropriate. An important example in 2022 includes the Philips Ventilator CPAP and BiPAP recall where the FDA invoked rarely used regulatory authority to order that Philips notify all health professionals and other persons, which includes millions of impacted patients, about the recall and the serious risk posed by the polyester-based polyurethane (PE-PUR) foam in the devices.

While patients remain our focus, we recognize that this important work cannot be done without engaged and knowledgeable employees. Under our newly-launched 2022-2025 Strategic Priorities, we have designed strategies to incorporate diversity, equity, inclusion, and belonging into hiring practices, as well as enhance employee engagement and wellness programs to ensure that CDRH maintains a healthy, talented, and diverse workforce. We are eager to see the positive impact these changes will have on our organization moving forward.

As we look now to 2023, we will continue our goal of assuring CDRH is well-prepared for the coming innovations in technology and unanticipated national health challenges, while engaging with and continuing to serve the American public. I look forward to it.

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

# CDRH BY THE NUMBERS



CUSTOMER  
SERVICE  
RATING

2,011  
DEDICATED CDRHERS



238,000  
REGULATED DEVICES



18,800  
SUBMISSIONS RECEIVED



27,000  
DEVICE MANUFACTURING FIRMS



57  
GUIDANCES/REVISIONS



## DEVICE INNOVATION

14  
STeP REQUESTS GRANTED

19  
SUBMISSIONS DESIGNATED AS  
BREAKTHROUGH DEVICES RECEIVED  
MARKETING AUTHORIZATION

84  
NOVEL DEVICES RECEIVED  
MARKETING AUTHORIZATION

135  
SUBMISSIONS DESIGNATED  
AS BREAKTHROUGH DEVICES

11  
COLLABORATIVE  
COMMUNITIES

## CDRH SAFETY-RELATED COMMUNICATIONS

30  
SAFETY  
COMMUNICATIONS

15  
LETTERS TO HEALTH  
CARE PROVIDERS

66  
CLASS 1 RECALL  
AMPLIFICATIONS

7  
ADVISORY  
COMMITTEE  
MEETINGS

9  
PUBLIC  
MEETINGS

@ 610  
EXTERNAL  
EMAILS

f 714  
TWEETS

t 54  
FACEBOOK  
POSTS

in 194  
LINKEDIN  
POSTS





# PANDEMIC RESPONSE

## COVID-19

**While CDRH has made enormous strides in reducing our review backlog due to the pandemic, a sustained workload associated with COVID-19 response continued in 2022.** Over the past year, the focus has shifted toward addressing the impact of new COVID-19 variants on device safety and effectiveness, as well as establishing transition strategies for existing COVID-19 devices, converting devices from emergency use authorization (EUA) to traditional marketing authorization, strengthening supply chain resilience, and preparing for future public health emergencies.

This year, we continued to respond to the COVID-19 pandemic, reviewing and authorizing a significant number of diagnostic tests and continuing our high levels of outreach and engagement with the test developer community, patients, consumers, caregivers, providers, and government agencies.

765

MEDICAL DEVICES AUTHORIZED IN 2022

2,831

MEDICAL DEVICES AUTHORIZED  
TO ADDRESS THE PHE

(EUA & TRADITIONAL MARKETING AUTHORIZATION)

### HIGHLIGHTS FROM THE YEAR INCLUDE:

#### Partnering with NIH RADx

to study the performance of antigen tests, including evaluating the impact of viral mutations such as the omicron variant; establishing the Independent Test Assessment Program (ITAP) to bring high quality COVID-19 antigen tests to the market in unprecedented timelines; and collaborating on the Test Us at Home (TUAH) research study to provide data supporting continued use of antigen tests in the setting of the omicron variant when adequate serial testing is performed, particularly for asymptomatic individuals.

#### Updating the Policy for COVID-19 Tests

to ensure continued patient and consumer access to tests while encouraging the transition of these important public health tools to traditional premarket review pathways. The updated policy describes the FDA's intent to review only a small subset of new EUA requests for diagnostic tests to best meet the needs of the public. At the same time, the FDA continued to encourage developers for all test types to pursue traditional marketing authorization through the De Novo classification or 510(k) clearance premarket review pathways.

#### Issuing a safety communication,

based on data from the TUAH research study, recommending that individuals repeat testing following a negative result on any at-home COVID-19 antigen test, whether or not the individual has symptoms. The FDA followed the safety communication with a revision to the intended uses for all authorized COVID-19 antigen tests, including home and point of care tests, and required updates to the labeling regarding repeat testing after a negative COVID-19 test result.

#### Issuing consumer-friendly information

for the public to determine the likelihood of having a COVID-19 infection and what to do next after an individual tests positive or negative.



# PANDEMIC RESPONSE



## BUILDING A RESILIENT SUPPLY CHAIN & RESPONDING TO SHORTAGES

The COVID-19 public health emergency (PHE) exposed weaknesses in our supply chain as the nation experienced shortages in critical devices such as personal protective equipment (PPE), ventilators, and other critical medical devices. The Coronavirus Aid, Relief, and Economic Security (CARES) Act gave the FDA, for the first time, authority related to device shortages (section 506J of the FD&C Act). However, these authorities remain limited and tied to a PHE. While CDRH has used this limited authority to better understand and monitor the complex web of supply chains that feed the medical device industry, to be more proactive in solving problems before they occur, we need comprehensive authority to best protect public health not tied to a PHE.

As of December 2022, we have dealt with 455 potential and actual shortages, which translates to hundreds of thousands of device units that have been in shortage. We used the information we received from our CARES Act authorities to mitigate almost 350 of these 455 shortages; and used regulatory tools including guidances, regulatory flexibilities, EUA, and conservation strategies. CDRH also worked across the U.S. government to inform the use of non-regulatory mitigations, including the use of Defense Production Act (DPA) ratings, prioritization letters, and transportation prioritization.

We now publish a [device shortage list](#) to communicate to the public what devices we determine to be in shortage. Based on active monitoring and impact assessments, the device shortage list was updated four times in 2022.

President Biden signed executive orders in 2021 for a sustainable public health supply chain, and Congress provided the first resources CDRH has received to support the Center's efforts to mitigate and prevent medical device shortages. Since then, we have built the [CDRH Resilient Supply Chain Program \(RSCP\)](#) to address medical device supply chain vulnerabilities. The CDRH RSCP is a permanent program built on a foundation of strong partnerships to improve end-to-end visibility and resiliency. Under the CDRH RSCP, we are proactively communicating, collaborating, and engaging with patient advocates, health care providers, distributors, group purchasing organizations, manufacturers, and key component and material suppliers.

In June, we held a two-day [public workshop](#) to discuss ways to foster resiliency in the medical device supply chain, to seek input on the new CDRH RSCP, and to explore collaborations with government, private sector, and non-governmental organizations.

In August, we [removed N95 respirators](#) from the medical device shortage list due to increased domestic manufacturing. This action highlighted the collaborative efforts by the FDA, National Institute for Occupational Safety & Health (NIOSH), Occupational Safety and Health Administration (OSHA), and U.S. manufacturers to ensure adequate supply of these essential devices to U.S. health care workers.

## DIAGNOSTIC INNOVATION

Diagnostic innovation is critical to the delivery of high-quality patient care. In 2022, we supported the development of novel COVID-19 tests with advanced technologies to address the current pandemic and better position the U.S. for the next public health emergency.

Diagnostic devices also aid in developing innovative treatment methods from public health analytics and research. To maximize the use of diagnostic data for both individuals and populations, we must eliminate key barriers, including difficulty in the collection of valuable data from tests conducted at-home or in-clinic laboratories, a lack of interoperability/harmonization, and consistent erosion of accuracy as the data is transferred between systems. To address these challenges, we continue to champion the Diagnostic Data Program (DxD), aimed at improving diagnostic data quality and utility from in vitro diagnostics (IVDs). The DxD launched with two specific focus areas: (1) [Systemic Harmonization and Interoperability Enhancement for Laboratory Data \(SHIELD\)](#), and (2) Digital Diagnostics (over-the-counter [OTC] and point-of-care [POC] diagnostics). In 2022, the first cycle of extramural funding was executed under DxD, including 5 awards and 2 contracts. One of these awards included the Safe Health Systems (SAFE) for the Connected Diagnostics (SAFE CDx) Platform. This platform will help to enable accelerated development and deployment of connected diagnostics by facilitating standards-based diagnostic data capture, harmonization, and transmission between disparate systems within the existing healthcare ecosystem.

**First EUA-authorized COVID-19 diagnostic test** that [detects chemical compounds in breath samples](#).

**First EUA-authorized point of care test** to [detect COVID-19 and influenza A and B](#).



# PANDEMIC RESPONSE

## MPOX

In May 2022, mpox emerged as a new PHE. CDRH immediately began taking steps to ensure adequate testing capacity in the U.S. For example, in early May, the FDA and the CDC worked together on modifications to the existing FDA-cleared CDC test to increase testing capacity and accessibility. These and other actions facilitated tests being shipped to five commercial laboratory companies, in addition to use in over 65 designated CDC Laboratory Response Network (LRN) laboratories, quickly increasing testing capacity and access. Testing capacity rapidly increased from 6,000 tests per week at the beginning of the outbreak to 80,000 tests per week as of July 18 and through the rest of 2022. In parallel, CDRH engaged with the laboratory community and contacted commercial manufacturers to encourage and support the development of tests for mpox. A key part of CDRH's pre-emergency declaration work included monitoring testing and highlighting safety concerns, as noted in our [Safety Communication: For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results: FDA Safety Communication](#).

On September 7, HHS announced the declaration under section 564 of the Federal Food, Drug, and Cosmetic Act allowing the FDA to issue EUAs for mpox in vitro diagnostic tests. That same day, the FDA issued [guidance](#), with associated [voluntary EUA templates](#), outlining review priorities, enforcement policies, and validation and submission recommendations. This same-day publication highlights the proactive work that was being done by CDRH in preparation for the issuance of EUAs. On the same day of the declaration, CDRH also issued the first EUA for Quest Diagnostics. The first commercial test kit for mpox was authorized via EUA on October 7.

Since the beginning of the mpox outbreak, CDRH engaged early and often with the CDC, laboratories, commercial manufacturers, health care professionals, and consumers to facilitate the availability of mpox tests to people and communities who need them.

On September 21, CDRH held the [first virtual town hall](#) for developers to answer questions on test development and validation for EUAs for mpox. This work, and more, was all conducted on top of normal operating conditions, reaching beyond defined operating roles for employees, including continued COVID-19 response and transition work discussed previously, without recruitment of additional personnel.

## LOOKING AHEAD

As we continue to transition from the focus on COVID-19 response efforts to the new normal, CDRH continues to incorporate lessons learned from the pandemic into both future preparedness and daily operations. CDRH has conducted and published its own assessments on lessons learned. In addition, as part of the systematic review of the FDA's COVID-19 response, three separate assessments were performed on behalf of the FDA or by other parts of the U.S. government to evaluate the use of EUAs during the COVID-19 pandemic and provide recommendations for future PHE preparedness. CDRH is actively working to implement recommendations in these reports, including through collaboration with key stakeholders, to proactively prepare for inevitable future challenges and threats to public health.

- 1. HHS Office of the Inspector General (OIG):**  
["FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing"](#)
- 2. U.S. Government Accountability Office (GAO):**  
["FDA Took Steps to Help Make Tests Available: Policy for Future Public Health Emergencies Needed"](#)
- 3. FDA independent assessment by Booz Allen Hamilton:**  
["Emergency Use Authorization Assessment – Final Report"](#)

# 80,000

MPOX TESTS AVAILABLE  
PER WEEK AS OF JULY 18



# MDUFA V



**On September 30, 2022, the FDA User Fee Reauthorization Act of 2022 was signed into law, including authorizing the Medical Device User Fee Amendments (MDUFA) for the next five years.** This monumental reauthorization package includes not only a continuation of device user fees, but also substantial investment in the future of the agency's medical device program. As the program has evolved, the FDA and industry have successfully negotiated agreements to improve patient access to medical devices and streamline regulatory processes, all while better assuring the safety and effectiveness of devices that patients and health care providers depend upon.

MDUFA V funding will provide critical resources to the FDA medical device review program to support program improvements including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts, and expanded opportunities to ensure patient perspectives are an integral part of medical device development and evaluation. CDRH, industry, and key stakeholders, including patient and consumer advocates, collaborated extensively to incorporate novel features into the user fee agreement, including a new goal structure with opportunities for "add-on" payments, as well as creation of the Total Product Lifecycle (TPLC) Advisory Program (TAP). These novel features will help spur more rapid development and widespread patient access to safe, effective, high-quality medical devices of public health importance through early and frequent interactions with CDRH, and through coordination with patients, providers, and payers. MDUFA V also provides opportunities for the FDA to explore ways to improve patient science tools to advance health equity, helping to ensure all patients in the U.S. have access to safe and effective medical devices appropriate for our diverse population. The impact of the MDUFA V reauthorization will be felt throughout every corner of the Center, representing a true visionary and collaborative approach to medical device regulation and innovation.

Since reauthorization, CDRH has hit the ground running to meet the commitments of MDUFA V. In three short months, we have:

**Launched the [TAP Pilot](#)**



**Issued final guidance on [Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions](#)**

**Announced availability of the [CDRH Customer Collaboration Portal \(CDRH Portal\)](#) for all premarket submissions**

**Filled 26 MDUFA V positions**



# DEVICE INNOVATION

**For medical devices, the words “innovative” and “novel” do not simply mean “new.”** Innovative and novel devices provide benefits to patients such as by addressing an unmet need, or being safer, or more effective than currently available alternatives. Our commitment to providing patients in the U.S. with timely access to safe and effective innovative devices is captured in our [2022-2025 Strategic Priorities](#).

## UPSTREAM INNOVATION: ADVANCING REGULATORY SCIENCE

In 2022, CDRH participated in initiation of a number of significant partnerships and collaborations that have the potential to impact device innovation in a profound way.

- CDRH launched a [strategic partnership with the Veterans Health Administration \(VHA\)](#) to drive innovation in areas such as interoperability and the use of 5G technology in medical devices. This partnership is focused on technologies which can impact health equity and equality in underserved populations.
- Three NIH institutes are now directly funding opportunities to develop [Medical Device Development Tools \(MDDTs\)](#) in diverse areas, such as biocompatibility evaluation and diagnostic imaging for cancer. These tools, once qualified by CDRH, will benefit innovators across the medical device ecosystem.
- CDRH is a key player in a new National Science Foundation (NSF)-sponsored [Industry University Collaborative Research Center](#) focused on medical uses for augmented/virtual/mixed reality. These technologies will have a broad impact on the device community, including diagnostic and therapeutic devices, and CDRH's involvement in the early stages of technology development can help ensure such approaches are suitable for use.

## MARKETING AUTHORIZATIONS FOR NOVEL DEVICES

The novel devices we authorized for marketing in 2022 demonstrate the remarkable ability of device stakeholders and the FDA to effectively respond to public health needs. Novel technologies include those brought to market through the Premarket Approval (PMA), Humanitarian Device Exemption (HDE), and De Novo pathways, as well as a subset of those brought to market through the 510(k) pathway and authorized under EUA. This year, CDRH gave marketing authorization to 84 novel devices, despite another year of heavy workload and the continued demands of our PHE response for both COVID-19 and mpox.

### Lumipulse G β-amyloid ratio

First in vitro diagnostic test to evaluate patients aged 55 and older who present with cognitive impairments for Alzheimer's disease and other causes of cognitive decline.

### Lungfit PH

First of its kind device to generate nitric oxide gas from room air with a ventilator. It is intended to improve oxygenation and reduce the need for extracorporeal membrane oxygenation (ECMO) in newborn infants (>34 weeks gestation) with certain types of respiratory failure.

### The Cooral System

First device intended to cool the inside of the mouth during chemotherapy cancer treatment to reduce the likelihood and severity of oral mucositis, which is a common and debilitating complication from cancer treatments.

### Earlipoint System

Indicated for use in specialized developmental disabilities centers as a tool using a digital health platform to aid clinicians in the diagnosis and assessment of autism spectrum disorder in patients ages 16 months to 30 months.

### Organ Care System (OCS) Heart System

First device for the preservation of donation-after-circulatory death (DCD) hearts in a warm-beating state.



# DEVICE INNOVATION

## EXPEDITING PREMARKET SUBMISSIONS

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

For devices that offer important safety innovations but do not otherwise qualify for the Breakthrough Devices Program, the [Safer Technologies Program \(STeP\)](#) may be available. STeP is a voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program.

To help patients have more timely access to certain devices, we continued to finetune our voluntary programs which expedite development and review of Breakthrough and STeP devices. In 2022, CDRH granted breakthrough designation to 135 devices (752 total breakthrough designations since program inception in 2015) and granted marketing authorization to 19 breakthrough devices. In October, we issued for comment the draft guidance [“Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff,”](#) which proposes select updates to the current guidance that clarify how the Breakthrough Devices Program may be applicable to certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions in populations impacted by health and/or health care disparities. In 2022, 14 STeP requests were granted and over 30 requests were received for inclusion in the program.

Through CDRH’s Digital Transformation Initiative, we further streamlined the market authorization process by enhancing IT infrastructure and improving both internal and external user experience, which supports our ability to meet MDUFA V commitments. [The CDRH Customer Collaboration Portal \(CDRH Portal\)](#) was launched to act as a submission hub for internal and external stakeholders, providing near real time submission status. In July, a trial run began for some stakeholders to submit using [the electronic Submission Template And Resource \(eSTAR\)](#), an interactive PDF form that guides submitters through the process of preparing a comprehensive medical device submission. In October, the CDRH Portal was made available for anyone to register for an account to send CDRH eCopy or eSTAR premarket submissions online. This follows the issuance of our final guidance, [“Electronic Submission Template for Medical Device 510\(k\) Submissions”](#) in September, which identifies October 1, 2023, as the date in which the 510(k) electronic submission requirements will take effect.

# 135

BREAKTHROUGH DEVICE  
DESIGNATIONS IN TOTAL THIS YEAR







## CDRH SPOTLIGHT

### OTC HEARING AID FINAL RULE

On August 16, the FDA issued a [historic final rule](#) establishing a new category of over-the-counter (OTC) hearing aids, allowing certain hearing aids to be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist. This rule implemented bipartisan legislation directing the FDA to create a category of OTC hearing aids.

This action follows President Biden's [Executive Order](#) on Promoting Competition in the American Economy, which called for the FDA to take steps to allow hearing aids to be sold over-the-counter and set a 120-day deadline for action, which the FDA met.

The FDA finalized the rule after receiving and reviewing more than 1,000 public comments on the proposed rule issued on October 20, 2021.

This final rule creates greater access and innovation for hearing aids, allowing patients more affordable and equitable access to these high impact devices. When purchasing OTC hearing aids, the FDA reminds consumers to be vigilant and research device options that best suit their needs, including consulting their physician for severe hearing loss or special considerations.

Starting in October 2022, these devices hit the shelves and immediately provided a more equitable marketplace for the nearly 30 million adult Americans with perceived mild to moderate hearing loss.



# DEVICE INNOVATION

## DIGITAL HEALTH

Digital health technologies play an increasingly significant role in today's health care system, and Artificial Intelligence/Machine Learning, or AI/ML, is powering important advancements in this field. The FDA has already authorized more than 500 AI/ML-enabled medical devices, and more are under development. In 2022, CDRH's Digital Health Center of Excellence (DHCoE) made significant strides to advance health care by fostering responsible and high-quality digital health innovation.

CDRH continues to lead the development of new regulatory frameworks tailored to digital health technologies, while promoting consistent application of digital health policies. In September, CDRH issued the final guidance "Clinical Decision Support Software," clarifying the scope of the FDA's device oversight of clinical decision support software intended for health care professionals. CDRH also launched the "Digital Health Policy Navigator," an interactive tool that helps developers assess whether a particular software function meets the device definition, and if so, whether it is the focus of the FDA's oversight as a device. In September, CDRH issued the report "The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings," marking the conclusion of the Pre-Cert Pilot Program and taking an important step toward identifying regulatory approaches to software that can better promote and protect public health.

Augmented Reality and Virtual Reality, or AR/VR, are transforming health care, delivering altogether new types of treatments and diagnostics, and changing how and where care is delivered. As part of our ongoing efforts to advance equity in and awareness of digital health technologies used in health care, in July, the Patient Engagement Advisory Committee met to discuss and make recommendations on AR/VR medical devices, and factors

to consider when evaluating AR/VR devices. Thought-provoking discussion highlighted challenging areas for patients and health care providers around this technology, including insights into challenges related to AR/VR use among vulnerable populations. In December, CDRH launched a list of AR/VR medical devices legally marketed in the U.S. to increase transparency and access to information on AR/VR medical devices.

CDRH also continued to foster digital-health focused collaborations that advance public health. CDRH participated in international harmonization and convergence efforts, including publication of the final document "Machine Learning-enabled Medical Devices: Key Terms and Definitions" by the International Medical Device Regulators Forum (IMDRF) and by co-chairing the recently re-launched IMDRF Software as a Medical Device (SaMD) Working Group. In October, CDRH released a "Spotlight: Digital Health Regulatory Science Opportunities." The Spotlight highlights common digital health interest areas such as patient-generated health data, artificial intelligence and machine learning, cybersecurity, and interoperability, among other topics, and presents these current regulatory science areas of interest in digital health for all to consider.

# 500+

NUMBER OF AI/ML-ENABLED MEDICAL  
DEVICES AUTHORIZED BY THE FDA





# DEVICE SAFETY

In 2022, we continued to foster timely patient access to safe medical devices and prioritize our mission to protect and promote public health, with a goal of spurring innovation in device safety and ensuring new products are able to address unmet medical needs.

## RECALLS

Patients are at the core of our mission to protect and promote public health. We take seriously our role in communicating about both the benefits and risks of medical devices to support an informed public and strong health care system. In 2022, we amplified 66 Class I recall notifications.

### PHILIPS RESPIRONICS VENTILATOR, BIPAP, CPAP RECALL

In June 2021, Philips Respironics recalled certain ventilators, BiPAP, and CPAP machines because the polyester-based polyurethane (PE-PUR) foam used in these devices can break down and potentially result in serious injury, cause permanent impairment, and require medical intervention to prevent permanent injury. Throughout the recall, we have regularly and proactively engaged with Philips to protect the public health and safety of patients. This includes the need to fix the recalled devices and provide patients and providers with the information they need to make informed health decisions. Our actions have demonstrated our commitment to use the tools available to us to hold companies accountable. While all our work may not be immediately visible to the public, the push toward resolution is constant.

## CDRH STEPS INCLUDE:

**Requiring Philips Respironics** to notify patients and others of the company's June 2021 recall after the FDA determined the company's notification efforts to date have been inadequate.

**Providing Philips** with a notice of opportunity for an informal hearing on CDRH's proposal that a section 518(b) order should be issued. Such an order could have required Philips Respironics to submit a plan for the repair, replacement, and/or refund of the purchase price of recalled devices that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated.

**Working with consumers**, patient organizations, and health care professional societies to understand and address common questions and concerns related to this recall.

**Working with other manufacturers** and government partners to try to help make available more BiPAP and CPAP machines.

**Performing careful evaluation** of the totality of information available to the FDA in determining appropriate next steps.

**Creating a CDRH Recall Response Team** in CDRH's Division of Industry and Consumer Education (DICE), a group of dedicated employees committed to ensuring patients and providers have ongoing contact with us for information about the recall.



# DEVICE SAFETY



## CYBERSECURITY

Exploitation of medical device cybersecurity vulnerabilities can lead to adverse impacts on patient care and patient safety. Cybersecurity incidents also have the potential to cause domestic supply chain disruptions, which could be particularly devastating in the case of a natural disaster or PHE, for example, when supplies are limited. The FDA plays an important role in ensuring the safety and effectiveness of medical devices in the face of potential cyber threats and working closely with our U.S. government partners and the entire ecosystem – industry, patients and health care providers and facilities – to mitigate cybersecurity risks.

In 2022, CDRH continued to ensure that connected medical devices are protected from cybersecurity threats to protect patients, including working with manufacturers throughout the entire product lifecycle. Based on the rapidly evolving landscape and increased understanding of threats and their potential mitigations, the FDA released Draft Guidance ["Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"](#) in April 2022 to incorporate input from stakeholders who provided comment to the FDA's 2018 Draft Guidance: "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." CDRH is also actively leading efforts to create globally harmonized principles by co-chairing the Medical Device Cybersecurity Guide working group of the International Medical Device Regulators Forum (IMDRF). The IMDRF cybersecurity working group released two draft documents in 2022 for public consultation: ["Principles and Practices for the Cybersecurity of Legacy Medical Devices"](#) and ["Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity."](#)

In October, we released a new video, ["Tips for Clinicians – Keeping Your Patients' Connected Medical Devices Safe"](#) to help clinicians discuss cybersecurity of connected medical devices with patients. In November, in collaboration with MITRE, CDRH updated the [Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook](#), a resource to help health care organizations prepare for cybersecurity incidents and preparedness response for medical device cybersecurity issues that impact device functions.



## MATERIAL SAFETY

In 2021, we partnered with ECRI to collate the current scientific knowledge base regarding the safety of materials that are commonly used in implantable medical devices, including the effects of those materials on patients over time. The project was completed in 2022, with [20 extensive reports](#) made publicly available covering diverse materials including polymers, metals and their alloys, and ceramic materials. These evaluations are part of CDRH's broader initiative to improve the safety of medical devices, particularly given our work with specific metal-containing implants after safety concerns were raised including for [metal-on-metal \(MoM\) total hip arthroplasty \(THA\) systems](#) and the [Essure System for Permanent Birth Control](#). This effort will help to provide innovators and medical device manufacturers with appropriate information for them to make more informed scientific decisions on materials of composition for devices. The next major objective of this program will be to assimilate all the information described above with information on the real-world performance of devices to help identify and define patient populations who may be at an elevated risk of adverse outcomes.



# DEVICE SAFETY



## HEALTH OF WOMEN STRATEGIC PLAN

In January 2022, CDRH published the [Health of Women Program Strategic Plan](#), which lays out the framework to further the FDA's mission, including protecting and promoting the health of women, strengthening regulatory science, and identifying and addressing current and emerging issues in medical device research and regulation for the health of all women. CDRH initially issued a proposed strategic plan in September 2019 and considered public feedback to inform this plan and the need to understand the implications of sex and gender on the performance of medical devices in all individuals. With patients at the heart of this initiative and strategic plan, Health of Women is one element of the Center's commitment to advance health equity to ensure all women have access to innovative, safe, and effective medical devices. This year, CDRH developed a Portfolio of Women-Specific Medical Devices to identify research gaps in the health of women device ecosystem. The portfolio provides information (for example, device names, manufacturers, product codes, indications for use, cited regulations, recalls, etc.) about women-related device availability, safety, and effectiveness and will support efforts to identify current and future needs and address gaps in women-specific medical device research.

## REAL WORLD EVIDENCE / REAL WORLD DATA

Real World Evidence (RWE) / Real World Data (RWD) is used to monitor postmarket safety of medical devices, support regulatory, reimbursement, and coverage decisions, develop clinical trial designs, and create tools and guidelines for use in clinical practice. CDRH aims to foster the use of RWE to support regulatory decision-making. To further this goal, we continued to lead the evolution of the clinical evidence landscape by optimizing the National Evaluation System for health Technology (NEST), which develops RWE and promotes its use for regulatory purposes. We had several notable accomplishments this year, including:

**Funding a study to determine [how patients weigh benefits and risks associated with smooth and textured breast implants](#), including the risk of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), which appears more often in patients with textured breast implants. This resulted in a [safety communication](#) that was issued in September 2022.**

**To further advance the use of RWE** to support marketing authorization of diagnostic tests, CDRH, in collaboration with the Reagan-Udall Foundation, funded two research projects evaluating the real-world performance of IVDs to: 1) support COVID-19 IVD manufacturers in pursuing EUAs and/or traditional marketing authorizations, and 2) provide a blueprint for all IVD manufactures for future submissions.



## LOOKING AHEAD

Despite another demanding year, we made remarkable progress in 2022, continually innovating to meet new and evolving scientific advancements, patient needs, emerging threats, and changes in the medical device ecosystem. We accomplished so much because of the dedication, expertise, and innovative spirit of our employees—the reason behind our current and future successes. We stand ready to meet each new challenge and opportunity in 2023 as we continue our commitment to serve the American public and ensure our organization is well-positioned to fully achieve our mission and vision.



## INFORMATION

**Safety Communications:** [2022 Safety Communications | FDA](#)

**Guidances:** [Guidance Documents \(Medical Devices and Radiation-Emitting Products\) | FDA](#)

**Recalls:** [2022 Medical Device Recalls | FDA](#)

**Letters to Health Care Providers:** [2022 Letters to Health Care Providers | FDA](#)

**2022 Device Approvals:** [2022 Device Approvals | FDA](#)

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