



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

PROGRAMMATIC ACCOMPLISHMENTS



ANNUAL REPORT

CONTENTS

4 COVID-19 RESPONSE

- 4 OTC COVID-19 Tests
- 4 COVID-19 Communication and Engagement
- 5 Resilient Medical Device Supply Chain
- 6 CDRH Pandemic Response
- 7 COVID-19 Postmarket Actions

8 PATIENT SCIENCE AND ENGAGEMENT

- 9 Collaborative Communities

10 DEVICE SAFETY

- 10 Medical Device Safety Action Plan
- 11 Material Safety
- 11 Cybersecurity
- 12 Quality and Compliance Initiatives
- 12 Real-World Evidence

13 DEVICE INNOVATION

- 13 Novel Devices
- 13 Breakthrough Designation
- 14 Examples of Novel Devices
- 15 Breakthrough Devices in Action
- 15 Digital Transformation
- 16 Digital Health
- 17 OTC Hearing Aid Rule
- 17 Regulatory Science Tools

18 CUSTOMER SERVICE



1,900
DEDICATED “CDRHers”



236,000
REGULATED DEVICES



25,000
DEVICE MANUFACTURING
FIRMS



19,000
SUBMISSIONS RECEIVED

CENTER DIRECTOR'S MESSAGE

The past year presented the U.S. and the world with an extraordinary set of health-related challenges. The Center for Devices and Radiological Health (CDRH) and all of the FDA stepped up to shoulder our responsibilities for addressing these unique challenges – all while working hard to keep up with our ongoing mission of protecting public health and spurring medical device innovation. We have now granted emergency use authorization (EUA) or full marketing authorization to over 2,000 medical devices intended to prevent, diagnose, or treat COVID-19 and more than half of CDRH's workforce has been directly involved in the COVID-19 response.

It would be hard to overstate the impact the global pandemic had on our Center and the entire FDA, as it did for so many individuals, families, communities, organizations, and populations around the world. This public health emergency became central to our work and pushed us into a continuous all-hands-on-deck status, working in some cases literally around the clock to facilitate the development and availability of pandemic-related medical devices as quickly and safely as possible.

We're proud that the results helped to assure the availability of accurate and reliable diagnostic tests, personal protective equipment (PPE), ventilators, and other critical devices and supplies for health care providers and patients. As one example, in 2021 we authorized 15 additional over-the-counter (OTC) COVID-19 tests for at-home use in record times—in some cases in less than a week.

While our efforts this past year – perhaps the busiest in the Center's 40-year history – continued to be driven by the pandemic, we could not and did not take our eyes off our other, ongoing responsibilities. As a result, we achieved many important milestones and accomplishments, in addition to those related to this public health emergency. We continued to prioritize patient and consumer health and well-being by facilitating device safety and innovation, advancing regulatory science, incorporating patients' perspectives in the work we do, and providing transparent and efficient regulatory pathways. Wherever our work was focused, a single overarching vision kept us moving forward: that patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

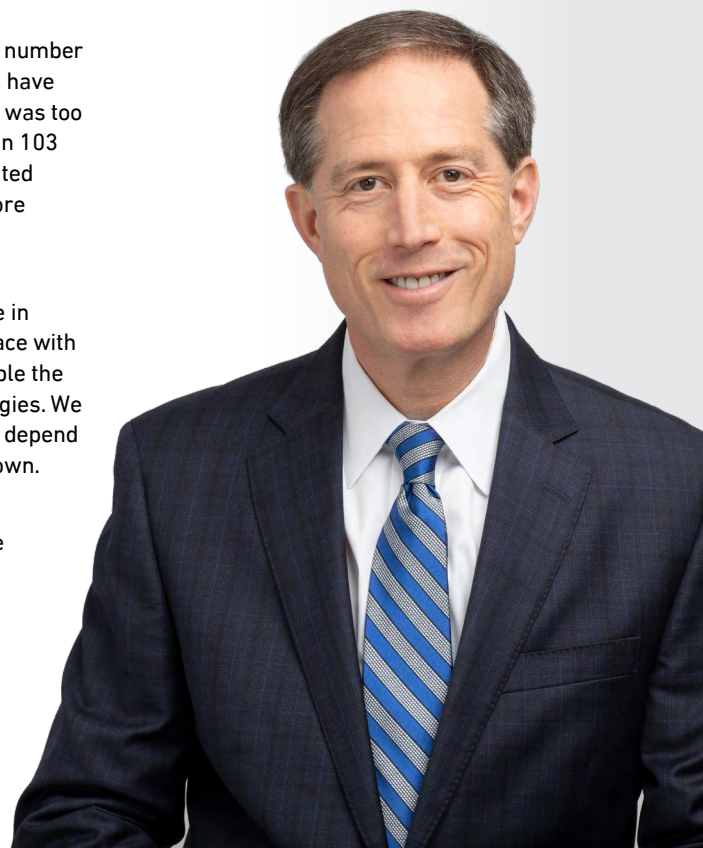
One way that we are measuring the success of our efforts is through tracking the number of innovative medical technologies being brought to the U.S. first so that patients have access to the safest and most innovative devices available. A decade ago, the U.S. was too often behind in this regard. But we are gratified to see our efforts have resulted in 103 novel devices receiving marketing authorization in 2021, despite the unprecedented demands of our pandemic response. Spurring innovation in developing safer, more effective devices is key to improving patient care and quality of life.

Still, the U.S. medical device community is in an increasingly competitive global marketplace, and the number, complexity and intensity of the challenges we face in facilitating availability of these devices to U.S. patients is only growing. To keep pace with these challenges, the FDA must ensure it has the resources and the tools to enable the development of and timely access to the most promising and emerging technologies. We know that U.S. patients are counting on us to succeed, and their health and safety depend on it. Everyone at the FDA will do what it takes to make sure we don't let them down.

As we look now to 2022, it is my sincere hope that we are all headed toward brighter days. Our Center and the entire FDA stand ready to meet each challenge and opportunity in our continuing commitment to public health.

Jeff Shuren, M.D., J.D.,
Director, Center for Devices and Radiological Health

“Our Center and the entire FDA stand ready to meet each challenge and opportunity in our continuing commitment to public health.”



COVID-19 RESPONSE

The FDA was called upon in 2021 to continue our critical role in strengthening the public health response to the COVID-19 pandemic. CDRH did much to support that effort, even while continuing to bring a growing portfolio of innovative devices to U.S. patients. The Center and the entire FDA have worked tirelessly this past year to cope with a huge volume of submissions, and have done so with limited resources. As we did in the prior six public health emergencies, the FDA employed its EUA authorities to facilitate the availability of critical medical devices, including COVID-19 tests, personal protective equipment (PPE) and ventilators. The result was authorizations in record time for a wide variety of devices that address public health needs during this public health emergency (PHE).

OTC COVID-19 TESTS

Since the beginning of the pandemic, CDRH has prioritized at-home tests, balancing speed with safety to ensure COVID-19 tests are accurate and reliable as supported by valid scientific evidence. In 2021, CDRH authorized 15 additional over-the-counter at-home tests, bringing the total to 16 and resulting in hundreds of millions of additional OTC tests available monthly to American consumers. CDRH also took several additional steps, including:

- **Facilitating OTC COVID-19 test availability** by issuing updated templates for EUA requests to streamline authorization of OTC tests.
- **Partnering with the National Institutes of Health (NIH)** on the Independent Test Assessment Program (ITAP) to support the FDA's evaluation of OTC COVID-19 tests that have the potential for manufacturing at significant scale, which resulted in two OTC authorizations of tests this year.
- **Triaging our review efforts** to focus on tests that ensure the biggest public health impact.



COVID-19 COMMUNICATION AND ENGAGEMENT

To help combat the COVID-19 pandemic, the FDA and CDRH staff have gone well beyond normal operating procedures to work with all stakeholders to help ensure the availability of appropriately safe and effective COVID-19-related devices as quickly as possible. From early in the pandemic, CDRH has actively reached out to and engaged other government agencies, medical device developers and international regulatory agencies, among other stakeholders. CDRH continues to hold weekly virtual town halls with industry to address COVID-19 test development and validation, as well as additional webinars and town halls to discuss policies and questions, including PPE, 3D printed swabs and manufacturing disruptions during the public health emergency. CDRH staff have also interacted frequently with developers through the Pre-Emergency Use Authorization (PEUA) process, including rolling reviews of information that helped to further expedite emergency use authorization of critical medical devices for patients and our health care professionals on the front lines.

RESILIENT MEDICAL DEVICE SUPPLY CHAIN

Throughout the COVID-19 public health emergency, CDRH has taken many actions to help ensure that patients and health care providers have timely and continued access to medical devices. The investments outlined in the [FDA's FY 2022 budget](#) include \$21.6 million for a new Resilient Supply Chain and Shortages Prevention Program (RSCSPP) in CDRH. This funding will for the first time provide resources to establish a permanent program for U.S. supply chain resilience for medical devices. The program will build on the work done to implement the CARES Act during the COVID-19 public health emergency, focusing on strengthening the domestic supply chain through investments in preventive measures, identifying potential medical product supply shortfalls, continuing surveillance and rapid intervention.

**\$21.6
million**

FOR NEW RESILIENT SUPPLY
CHAIN AND SHORTAGES
PREVENTION PROGRAM
(RSCSPP) IN CDRH

**1,000
12**

MANUFACTURERS
AND SUPPLIERS

COUNTRIES



TIMELINE: JANUARY 1, 2020 - DECEMBER 31, 2021

CDRH has also taken many actions to help avoid and address medical device shortages during the pandemic, including:

- **Maintaining a public medical device shortage list** and working with over 1,000 manufacturers and suppliers in more than 12 countries, across health care to manage and monitor supply chain shortages identified on the [FDA shortages list](#), as well as other devices deemed critical to public health during this pandemic.
- **Performing more than 2 dozen shortage assessments** on signals from manufacturers, distributors, and other governmental partners, pertaining to PPE, COVID-19 testing supplies and equipment, ventilator and other related device shortages.
- **Repurposing ~130 employees** to work full or part time on shortages.
- **Reaching out to manufacturers and distributors** to assess supply chain vulnerabilities.
- **Collaborating with the Office of the Assistant Secretary for Preparedness and Response (ASPR)** for shortage assessment and shortage mitigation.
- **Continuing to implement new shortage authorities** granted under the CARES Act.
- **Serving as a clearing house for testing supply alternatives** (which started in March 2020), helping to expand allowable specimen types for swabs.
- **Identifying common material issues** that informed diagnostics Industrial Base Expansion funding opportunities (for example, swabs, pipette tips, COVID test kits and raw materials) to allow for increased availability of diagnostic products.



CDRH PANDEMIC RESPONSE

TIMELINE: JANUARY 1, 2020 - DECEMBER 31, 2021

EMERGENCY USE AUTHORIZATIONS

CDRH authorized **15 times more** Emergency Use Authorization (EUA) requests than during all previous public health emergencies combined.

2,039

MEDICAL DEVICES AUTHORIZED
(EUA AND FULL MARKETING AUTHORIZATION)



3,738

**ORIGINAL EUA
REQUESTS RECEIVED**



1,172

**EUA SUPPLEMENTS
RECEIVED**



2,628

PRE-EUAs RECEIVED

INCLUDING

**IN VITRO
DIAGNOSTICS (IVDS)**

290
MOLECULAR

87
ANTIBODY

43
ANTIGEN

4
OTHER

**OTHER MEDICAL
DEVICES**



269
PERSONAL PROTECTIVE
EQUIPMENT (PPE)

119
VENTILATORS

52
OTHER

NON-EUA DEVICES
(cleared, approved, or granted)

60
TESTS/TEST
SUPPLIES

532
PERSONAL PROTECTIVE
EQUIPMENT (PPE)

94
VENTILATORS

489
OTHER

WORKFORCE



50%+ of CDRH's workforce has been directly involved in the COVID-19 response effort, and many others increased their non-COVID workload to help.

630,515 CDRH staff hours have been spent on COVID-19 work. This time equates to approximately **400** people or about a fifth of all CDRH staff working full-time for **1 year**.

70 Commissioned Corps officers have been **deployed 134 times** to support the COVID-19 response, including assisting at testing centers as well as direct patient care.

OUTREACH

13 EUA TEMPLATES

21 GUIDANCE DOCUMENT REVISIONS

28 PUBLISHED GUIDANCE DOCUMENTS

97 WEBINARS AND VIRTUAL TOWN HALLS

341 FREQUENTLY ASKED QUESTIONS

412,312 INQUIRIES ADDRESSED

Partnership with National Institutes of Health (NIH)/National Cancer Institute (NCI) to conduct independent evaluation of serology test performance.

Partnership with NIH RADx to drive testing innovation by supporting manufacturers to mature, scale and commercialize tests, particularly the FDA authorization of point-of-care (POC) and at-home tests.

TIMELINE: JANUARY 1, 2020 - DECEMBER 31, 2021

COVID-19 POSTMARKET ACTIONS

CDRH continues to monitor COVID-19-related medical devices once they reach the market. CDRH imposes Conditions of Authorization for EUAs specific to device type, such as adverse event reporting requirements or requiring developers to monitor the impact of variants on test performance. If there are signs that device safety or effectiveness may have been compromised, CDRH takes prompt action to mitigate the risk to patients, such as removing tests from notification lists or taking regulatory action. These efforts help assure devices are appropriately monitored and studied post authorization.

COVID-19 DEVICE POSTMARKET METRICS



45 WARNING LETTERS ISSUED (2021)

64 DEVICES RECALLED (2021)

263 EUAS REVOKED (COVID-19 PHE TOTAL)

315 TESTS REMOVED FROM NOTIFICATION LISTS (COVID-19 PHE TOTAL)

PATIENT SCIENCE AND ENGAGEMENT

Patients are at the heart of what we do. CDRH has been working to increase the presence of patient input throughout the medical device ecosystem. The Patient Science and Engagement Program is a team of social scientists, health economists, statisticians, clinical providers and other experts committed to engaging with patients as partners, and to including patients' perspectives into medical device development and evaluation. The Patient Science and Engagement Program team supports the Patient Engagement Advisory Committee (PEAC), as well as patient engagement activities focused on medical devices. In October, the PEAC met to discuss and make recommendations on the FDA's medical device recall approach, how to effectively communicate recall information to patients and the public, and ways to assure the patient perspective is incorporated into the FDA and industry's benefit-risk recall decision-making. CDRH routinely incorporates patient-reported outcome (PRO) measures into its decision-making, supporting CDRH's goal of integrating structured patient experience data into the regulatory process. In fact, over half of all Premarket Approval (PMA), Humanitarian Device Exemption (HDE) and De Novo submissions consistently include patient-reported outcomes in their clinical studies to support regulatory decision-making. CDRH also encourages the medical device industry to consider the patient preference in the evaluation of medical devices. As of December 31, 2021, the medical device industry has completed or is conducting 25 Patient Preference Information (PPI) studies to support regulatory use of the data. CDRH continues to advance patient science methods through virtual education and collaboration in over 20 research projects.



“CDRH has been working to **increase the presence of patient input** throughout the medical device ecosystem.”

COLLABORATIVE COMMUNITIES



2020 TARGET GOAL

Participate in at least **10** collaborative communities.



RESULTS

By December 31, 2020, CDRH was a participant in **10** collaborative communities; by August 2021, CDRH was a participant in **12** collaborative communities.

Collaborative Communities are a continuing forum in which private- and public-sector members work together on medical device challenges to achieve common objectives and outcomes, solve shared challenges, and leverage collective opportunities. Although CDRH does not establish collaborative communities, staff participate as members of the medical-device ecosystem, which may include national and international stakeholders such as device manufacturers, clinicians, patients, payors, academics, regulatory bodies and others. CDRH encourages prospective and existing communities to utilize the Collaborative Communities Toolkit to help foster community development and effective collaboration. We also published [this video](#) in August to share more information about participating in a collaborative community.



COLLABORATIVE COMMUNITIES WITH CDRH PARTICIPATION

1. Collaborative Community on Ophthalmic Imaging
2. National Evaluation System for health Technology Coordinating Center (NESTcc) Collaborative Community
3. Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community
4. International Liquid Biopsy Standardization Alliance (ILSA)
5. Xavier Artificial Intelligence (AI) World Consortium
6. Case for Quality Collaborative Community
7. Heart Valve Collaboratory (HVC)
8. Wound Care Collaborative Community
9. Pathology Innovation Collaborative Community (PICC)
10. RESCUE (REducing SuiCide Rates Amongst IndividUals with DiabEtes) Collaborative Community
11. MedTech Color Collaborative Community
12. Digital Health Measurement Collaborative Community (DATAcc)

DEVICE SAFETY

CDRH's mission is to protect and promote public health, with a goal of spurring innovation and facilitating patient access to new products that are safer and more effective and that address unmet medical needs. We consider our role in fostering timely patient access to safe medical devices that meet their health care needs a top priority for the Center.

MEDICAL DEVICE SAFETY ACTION PLAN

CDRH's Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health laid out CDRH's ongoing efforts to encourage innovation to improve safety, detect device risks earlier and keep doctors and patients better informed, as well as steps the Center would continue to take to further enhance safety. The Medical Device Safety Action Plan identifies 5 key areas for CDRH action, and we have made significant advancements in each area this year.

- 1. Establish a robust medical device patient safety net in the United States.**
- 2. Explore regulatory options** to streamline and modernize the process of rapidly mitigating postmarket problems with devices.
- 3. Spur innovation to develop safer medical devices.** In 2021, we launched the Safer Technologies Program (STeP) and we began receiving STeP entrance requests in March 2021.
- 4. Advance medical device cybersecurity**, as discussed below.
- 5. Integrate CDRH premarket and postmarket offices and activities** to advance a Total Product Life Cycle (TPLC) approach to device safety.



CDRH SAFETY-RELATED COMMUNICATIONS

21 SAFETY COMMUNICATIONS

22 LETTERS TO HEALTH CARE PROVIDERS

57 CLASS I RECALL AMPLIFICATIONS



688 EXTERNAL EMAILS

717 TWEETS

MATERIAL SAFETY

In May 2021, CDRH [released a discussion paper](#), “Conveying Materials Information about Medical Devices to Patients and Health Care Providers: Considerations for a Framework,” an important step in our ongoing work to improve patient safety by increasing the awareness of the materials used in medical devices. The paper is a direct outcome of the feedback we received from the November 2019 advisory committee meeting. The meeting and the paper underscore the value we place on obtaining insight from stakeholders to help inform and shape our decision-making. Also, in 2021, we partnered with ECRI to create and publish Medical Device Material Safety Summaries for materials that are commonly used in implantable medical devices, including the effects of those materials on patients over time. As of December 31, 2021, the first 4 safety summaries—on magnesium, polypropylene, polyurethanes and siloxanes—have been published on the [CDRH website](#). Additional summaries will be published on a continuing basis.

In October, CDRH took several actions to strengthen breast implant risk communication and help ensure patients considering breast implants have access to critical risk information. This included new product labeling that includes a boxed warning and a patient decision checklist, orders to restrict the sale and distribution of breast implants to only health care providers and facilities that provide information to patients utilizing the patient brochure “Patient Decision Checklist,” which the patient and doctor both have to sign, and updated information on the status of breast implant manufacturer post-approval studies.

CYBERSECURITY

Many medical devices are becoming more technologically advanced, frequently depending on software, and on data connections to the internet and other devices. These advances can offer safer and more timely and convenient care. But they can also make devices vulnerable to cyber threats.

CDRH has taken steps throughout the total product lifecycle (TPLC) to ensure medical devices are cyber secure and that information about cybersecurity is communicated to patients, caregivers and health care providers. In October, CDRH participated in a webinar for industry, “Playbook for Threat Modeling Medical Devices,”



hosted by Medical Device Innovation Consortium. In November, MITRE/MDIC, sponsored by the FDA, published a playbook on best practices for basic threat-modeling concepts and processes related to medical devices. We also issued a response to the National Institute for Standards and Technology’s call for position papers, “[Response to NIST Workshop and Call for Position Papers on Standards and Guidelines to Enhance Software Supply Chain Security](#),” in May, which discussed established FDA practices and efforts in the greater medical device security ecosystem. This paper highlighted the FDA’s proposed recommendations for a Software Bill of Materials, a list of third-party software components that would be made available to medical device customers and users.

CDRH has also taken steps to ensure that information about cybersecurity is communicated to patients, caregivers and health care providers. In August, we released the discussion paper “[Strengthening Cybersecurity Practices Associated with Servicing of Medical Devices: Challenges and Opportunities](#)” (dated June 2021) to seek input from groups and individuals outside CDRH on cybersecurity issues unique to the servicing of medical devices. In October, we released “[Best Practices for Communicating Cybersecurity Vulnerabilities to Patients](#).” And in November, we launched the first CDRH video to offer practical steps for protecting medical devices and personal information, “[Cyber Vitals: Information for Patients’ Medical Device Health](#).”

QUALITY AND COMPLIANCE INITIATIVES

CDRH has completed substantial work within several programs and initiatives to facilitate patient access to high quality medical devices.

CDRH has also worked to strengthen the nation's public health infrastructure by accelerating the adoption of advanced manufacturing in the medical device industry.

- **Funded a Landscape Assessment project** to assess and benchmark advanced manufacturing efforts in the medical device industry compared to non-health care industries. Results of the assessment can be found in the [final report](#).
- **Launched an Advanced Manufacturing Clearinghouse**, a collaborative and independent third party that identifies and evaluates promising advanced manufacturing technologies.
- **Developed a proof of concept with Siemens Digital Industries** for a **digital twin of a ventilator**, an effort that demonstrates how digital technologies can identify and address supply chain problems, such as during COVID-19.

- **Partnered with the private sector** through the Medical Device Information & Analysis Sharing (MDIAS) Partnership and Platform to share, analyze and use medical device data in a protected environment. This partnership has incentivized medical device firms to increase automation and digital technology adoption. To advance that platform, we have established a governance board, developed version 1.0 of the data platform and completed a proof of concept.

REAL-WORLD EVIDENCE

Real-world data (RWD) and real-world evidence (RWE) play an important and growing role in health care. This data is used to monitor postmarket safety of medical devices, and to support regulatory decisions, reimbursement and coverage decisions, and clinical trial designs, as well as to develop tools and guidelines for use in clinical practice.

CDRH has met the MDUFA IV commitments to advance RWE by providing funding to [NESTcc](#) and leveraging RWD in place of postmarket studies, as summarized by CDRH in a report of 90 examples of RWE use in regulatory decisions. RWD has been brought into a variety of regulatory submissions, including PMA Panel Track Supplements, original PMAs, 510(k)s, De Novos and HDEs. CDRH continues to advance internal expertise, regulatory science and infrastructure in **5 categories**:



1
CONTINUED
SUPPORT TO
NESTCC AND MDIC

2
RWE
INFRASTRUCTURE
DEVELOPMENT

3
PROMOTION
OF RWE IN
REGULATORY
DECISION MAKING

4
POLICY
DEVELOPMENT

5
RESEARCH AND
PILOT PROJECT



DEVICE INNOVATION

Part of CDRH's vision is to spur innovation of new medical devices that are safer and more effective, and that address unmet medical needs. In 2021, we advanced our commitment to innovation in several notable ways.

NOVEL DEVICES

Novel technologies include those brought to market through the PMA, HDE and De Novo pathways, as well as a subset of those brought to market through Emergency Use Authorization (EUA), or the Breakthrough Devices Program. These technologies address an unmet need or may be safer or more effective than currently available alternatives.

Over the past decade, there were four times as many medical device approvals, authorizations and clearances of novel technologies as a result of the innovative policies and approaches CDRH has developed and implemented. In 2021, CDRH gave marketing authorization to 103 novel devices, an incredible achievement, especially during a time of increased demand on CDRH staff due to the COVID-19 pandemic. This highlights the commitment and dedication of CDRH staff to strengthen public health by bringing innovative devices to patients.

BREAKTHROUGH DESIGNATION

A critical aspect of protecting and promoting public health is facilitating access to innovative medical devices. The Breakthrough Devices Program offers manufacturers an opportunity to interact with CDRH's experts through several different program options to efficiently address topics as they arise during device development, evaluation and premarket review, so that manufacturers can receive timely feedback and expect prioritized submission review. The Breakthrough Devices Program has expanded significantly since 2018,



13

SUBMISSIONS DESIGNATED AS BREAKTHROUGH DEVICES RECEIVED FDA MARKETING AUTHORIZATION IN 2021



103

NOVEL DEVICES RECEIVED FDA MARKETING AUTHORIZATION IN 2021

213

SUBMISSIONS DESIGNATED AS BREAKTHROUGH DEVICES IN 2021

617

TOTAL SUBMISSIONS DESIGNATED AS BREAKTHROUGH DEVICES SINCE PROGRAM INCEPTION IN 2015

far exceeding expectations for breakthrough designation request and authorization volumes. In 2021, CDRH granted breakthrough designation to 213 devices (617 total breakthrough designations since program inception in 2015) and granted marketing authorization to 13 breakthrough devices (3 PMAs, 3 510(k)s, and 7 De Novos).

EXAMPLES OF NOVEL DEVICES

PROVIDED MARKETING AUTHORIZATION IN 2021 INCLUDE:

SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.



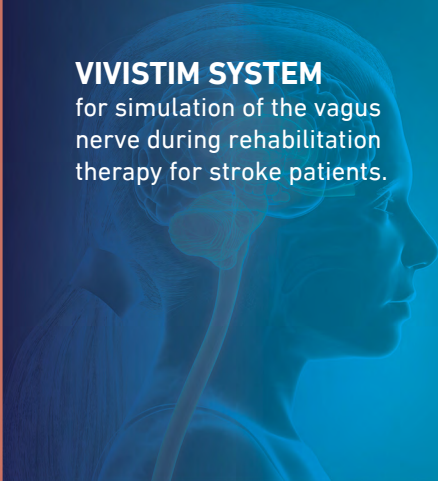
PAIGE PROSTATE, the first software based on artificial intelligence (AI) designed to identify an area of interest on the prostate biopsy image most likely to harbor cancer. The area can then be reviewed further by the pathologist if not already noted on initial review.

GI GENIUS a device that uses artificial intelligence based on machine learning to assist clinicians in detecting lesions (such as polyps or suspected tumors) in real time during colonoscopy.



PATIENT SPECIFIC TALUS SPACER the first in the world and first-of-its-kind, 3-D printed implant to replace the talus in the treatment of avascular necrosis of the ankle joint.

VIVISTIM SYSTEM for simulation of the vagus nerve during rehabilitation therapy for stroke patients.



COGNOA ASD DIAGNOSIS AID a machine learning-based software intended to help health care providers diagnose autism spectrum disorder in children 18 months through 5 years of age who exhibit potential symptoms of the disorder.

EASEVRX A PRESCRIPTION-USE IMMERSIVE VIRTUAL REALITY SYSTEM that uses cognitive behavioral therapy and other behavioral methods to help with pain reduction in patients 18 years of age and older with diagnosed chronic lower back pain.



HARMONY TRANSCATHETER PULMONARY VALVE SYSTEM the first in the world non-surgical heart valve to treat pediatric and adult patients with a native or surgically-repaired right ventricular outflow tract, who have severe pulmonary valve regurgitation.

PORTABLE NEUROMODULATION STIMULATOR (PONS) for short-term treatment of gait deficit due to multiple sclerosis (MS).



BREAKTHROUGH DEVICES IN ACTION

In 2021, CDRH authorized, cleared or approved 13 devices with breakthrough designation. These devices represent a range of intended uses and span regulatory pathways, highlighting the influence of this program throughout the Center. It also reflects the dedication of CDRH staff in helping industry bring innovative devices to market, especially on top of the increased workload demands during the ongoing COVID-19 public health emergency. The program's success demonstrates the benefits of extensive engagement with industry as a means of bringing innovative products to patients in need.

1. **CDRH approved the first in the world non-surgical heart valve** to treat pediatric and adult patients with a native or surgically repaired right ventricular outflow tract (RVOT), the part of the heart that carries blood out of the right ventricle to the lungs. The device is designed for patients who have severe pulmonary valve regurgitation (blood leaking backward into the right lower chamber of the heart), a condition that often results from congenital heart disease. The device, called the Harmony Transcatheter Pulmonary Valve (TPV) System, is intended to improve blood flow to the lungs in patients with severe pulmonary valve regurgitation without open-heart surgery, which is the current standard of care.
2. **CDRH also authorized marketing of a new device indicated for use in patients 18 and older undergoing stroke rehabilitation** to facilitate muscle re-education and for maintaining or increasing range of motion. The Neuroolutions IpsiHand Upper Extremity Rehabilitation System (IpsiHand System) is a Brain-Computer-Interface (BCI) device that assists in rehabilitation for stroke patients with upper extremity or hand, wrist and arm disability. Post-stroke rehabilitation helps individuals overcome disabilities that result from stroke damage. The IpsiHand System uses non-invasive electroencephalography (EEG) electrodes instead of using an implanted electrode or other invasive feature to record brain activity.

As mentioned above under the Medical Device Safety Action Plan, CDRH established the STeP program in 2021, including publishing final guidance and granting STeP designation for the first devices.



DIGITAL TRANSFORMATION

There are currently more than 30 data systems used in CDRH for the review and surveillance of medical devices. However, they are outdated, complex, fragmented and time-consuming to use. CDRH's Digital Transformation initiative aims to create new systems to improve the experience of users both internal and external to CDRH; to enhance CDRH's ability to accept, store, analyze and distribute data; and to digitalize CDRH's programs and operations.

In June, we launched the Decision Management Portal (DMP), a new internal platform that will provide a single location where CDRH staff can see all of their work through one interface, and in November, we launched the Medical Device Report (MDR) Review product, the first workflow within the DMP that transforms the way we review MDRs from the heavily customized legacy system to the new digital transformation platform, enabling improved business process and increased capacity around the review of MDRs. The Submission Memo and Review Template (SMART) for 510(k) and De Novo reviews represents one of the most impactful CDRH changes in years. SMART is an automated guide used by reviewers to evaluate information across disciplines, increasing the efficiency and consistency of the premarket review process. In September 2021, we also issued the draft

guidance “[Electronic Submission Template for Medical Device 510\(k\) Submissions](#)” and launched the [Voluntary electronic Submission Template And Resource \(eSTAR\) Pilot Program](#). The voluntary 510(k) eSTAR is an interactive PDF form that closely follows the order and content of the 510(k) review as laid out in the SMART templates, while standardizing the format and enhancing the quality of submissions. CDRH has also added the ability to prepare De Novo requests in the eSTAR. Voluntary eSTAR De Novo requests can be submitted to the FDA on or after January 3, 2022, which is the effective date of the De Novo final rule which was published on October 5, 2021.

DIGITAL HEALTH

From mobile medical apps and software to artificial intelligence (AI) and machine learning (ML), digital health technology has the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual. CDRH established the [Digital Health Center of Excellence \(DHCoE\)](#) to empower patients, health care practitioners, researchers and medical device firms to advance health care by fostering responsible and high-quality digital-health innovation. The DHCoE has accomplished much toward this goal, particularly with respect to software as a medical device (SaMD).

An increasing number of medical devices have software that incorporates AI, and the subset of AI known as ML. Since 1997, CDRH has [reviewed and authorized](#) over 300 devices with AI/ML across many different fields, including more than 50 authorized in 2021 alone. Most devices that rely on AI/ML fall into the category of SaMD, or software intended to perform one or more medical purposes without being part of a hardware medical device. In 2020, we launched the Software Precertification (Pre-Cert) Pilot Program to help develop a more streamlined and efficient regulatory model for SaMD in the U.S.

In January, CDRH released a [5-part AI/ML-Based SaMD Action Plan](#), which describes a multi-pronged approach to advance the FDA’s oversight of AI/ML-based medical software. To fulfill part of the Action Plan, CDRH held a public workshop in October on the transparency of AI/ML-enabled medical devices. Additionally, in September, CDRH launched a list of artificial intelligence and machine



CDRH has reviewed and authorized **over 300 devices** with AI/ML across many different fields, including more than **50** authorized in 2021.



learning (AI/ML)-enabled devices legally marketed in the U.S. The DHCoE developed this list to increase transparency and access to information on AI/ML-based medical devices. In October, CDRH, Health Canada and the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) jointly issued the [Good Machine Learning Practice \(GMLP\) for Medical Device Development: Guiding Principles](#) to promote safe, effective and high-quality medical devices that use AI/ML.

In December, the agency issued a cross-Center draft guidance, “[Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders](#)” to provide recommendations to sponsors, investigators and other stakeholders on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations that are evaluating medical products.

OTC HEARING AID RULE

In October 2021, CDRH proposed a landmark rule to establish a new category of over-the-counter (OTC) hearing aids, implementing a key provision of the Over-the-Counter Hearing Aid Act enacted in the FDA Reauthorization Act of 2017. When finalized, this rule would allow certain hearing aids to be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist. The rule aims to facilitate innovation and increase competition by lowering the barriers to entry for new hearing aid manufacturers, while also assuring the safety and effectiveness of OTC and prescription hearing aids.

REGULATORY SCIENCE TOOLS

The Medical Devices Development Tools (MDDT) program is a way for CDRH to qualify tools that medical device sponsors can choose to use in the development and evaluation of devices. These tools include biomarker tests, clinical outcome assessments and non-clinical assessment models such as animal or computational models. All of these tools can play an important role in helping CDRH understand how medical devices meet safety, effectiveness and other performance criteria. These tools also increase predictability for industry, enabling medical device sponsors to use qualified tools in approved contexts and know they will be accepted by CDRH, without the need to reconfirm their suitability and utility.

In addition to the qualification of MDDTs, CDRH has continued to collate a catalog of Regulatory Science Tools. The Catalog of Regulatory Science Tools provides a peer-reviewed resource for companies to use where standards and MDDTs do not yet exist. The tools reduce the need for device developers to design ad-hoc test methods and allow them to focus their limited resources on how well their new product works, rather than on how to test it. To further accelerate patient access to innovative, safe and effective medical devices, CDRH's Office of Science and Engineering Laboratories (OSEL) plans to collaborate with NIH/NCI to develop new tools, create a broader network of tool innovation and consider third-party review of certain MDDTs.



MDDTS SUMMARY

- 1 BIOMARKER TEST
- 4 NON-CLINICAL ASSESSMENT MODELS
- 5 CLINICAL OUTCOME ASSESSMENTS



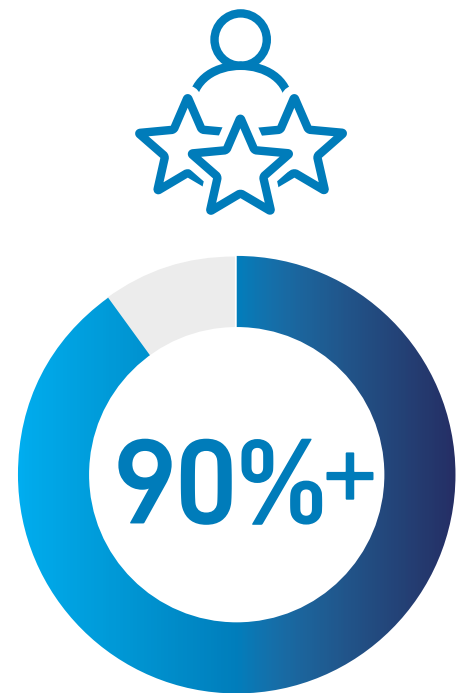
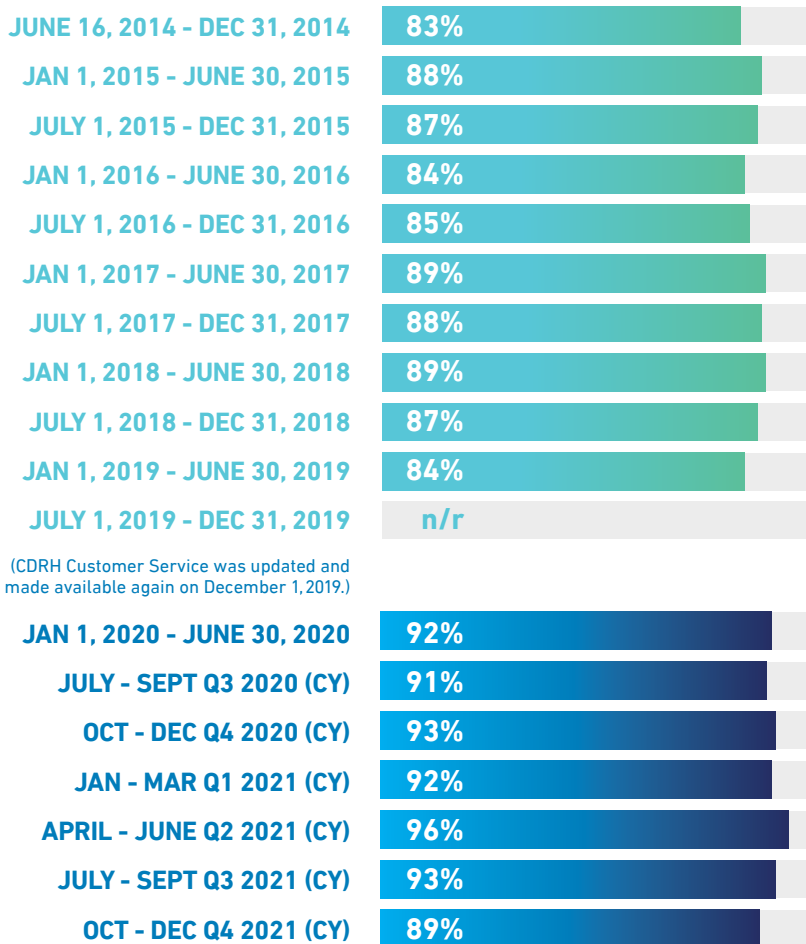
REGULATORY SCIENCE TOOLS SUMMARY

- 11 PHANTOMS
- 37 COMPUTATIONAL MODELS AND SIMULATIONS
- 69 METHODS

CUSTOMER SERVICE

Providing a high level of customer service is a high priority for CDRH. Improving our interactions with stakeholders and colleagues supports better regulatory outcomes, which in turn advances our public health mission. Since 2014, CDRH has been tracking customer-service satisfaction and collecting stakeholder feedback through our [customer service survey](#). We have consistently hit our goal of 90% satisfaction since the beginning of 2020, and in 2021, we reached a peak of 96%. CDRH will continue to track feedback and evaluate ways to identify customer needs while maintaining our regulatory obligations.

As evidenced by this report, quality is a cornerstone of our work. CDRH's Quality Management and Organizational Excellence (QMOE) Program has made tremendous progress since the ISO 9001:2015 certification in 2018. To continue to build on this success, CDRH will implement new systems and services to promote transparency and collaboration within the Center, emphasize stakeholder involvement and accommodate planned and ad-hoc improvements in the next year.



**SATISFACTION SINCE
THE BEGINNING OF 2020**

CONTACT INFORMATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH | FDA

Web: [Division of Industry and Consumer Education \(DICE\)](#)

Phone: 1(800) 638-2041 or (301) 796-7100

Email: DICE@fda.hhs.gov

Follow CDRH on social media for updates throughout the year:

 [@FDADeviceInfo](#)

 [@FDA](#)

 [FDA LinkedIn](#)