

MDUFA VI

Public Meeting

August 4, 2025

**Center for Devices and Radiological Health
U.S. Food and Drug Administration**

Begins at 10:00AM

Welcome & Introduction

Eli Tomar, J.D., M.P.H

*Deputy Director, Office of Policy
Center for Devices and Radiological Health*

Your Feedback



Docket:

<https://www.regulations.gov/>

Docket No. FDA-2025-N-1157



Email Address:

MDUFAVIReauthorization@fda.hhs.gov

Opening Remarks

Martin Makary, M.D., M.P.H.

FDA Commissioner

CDRH Update

Michelle Tarver, M.D., Ph.D.

Director

Center for Devices and Radiological Health

Patients are at the Heart of What We Do

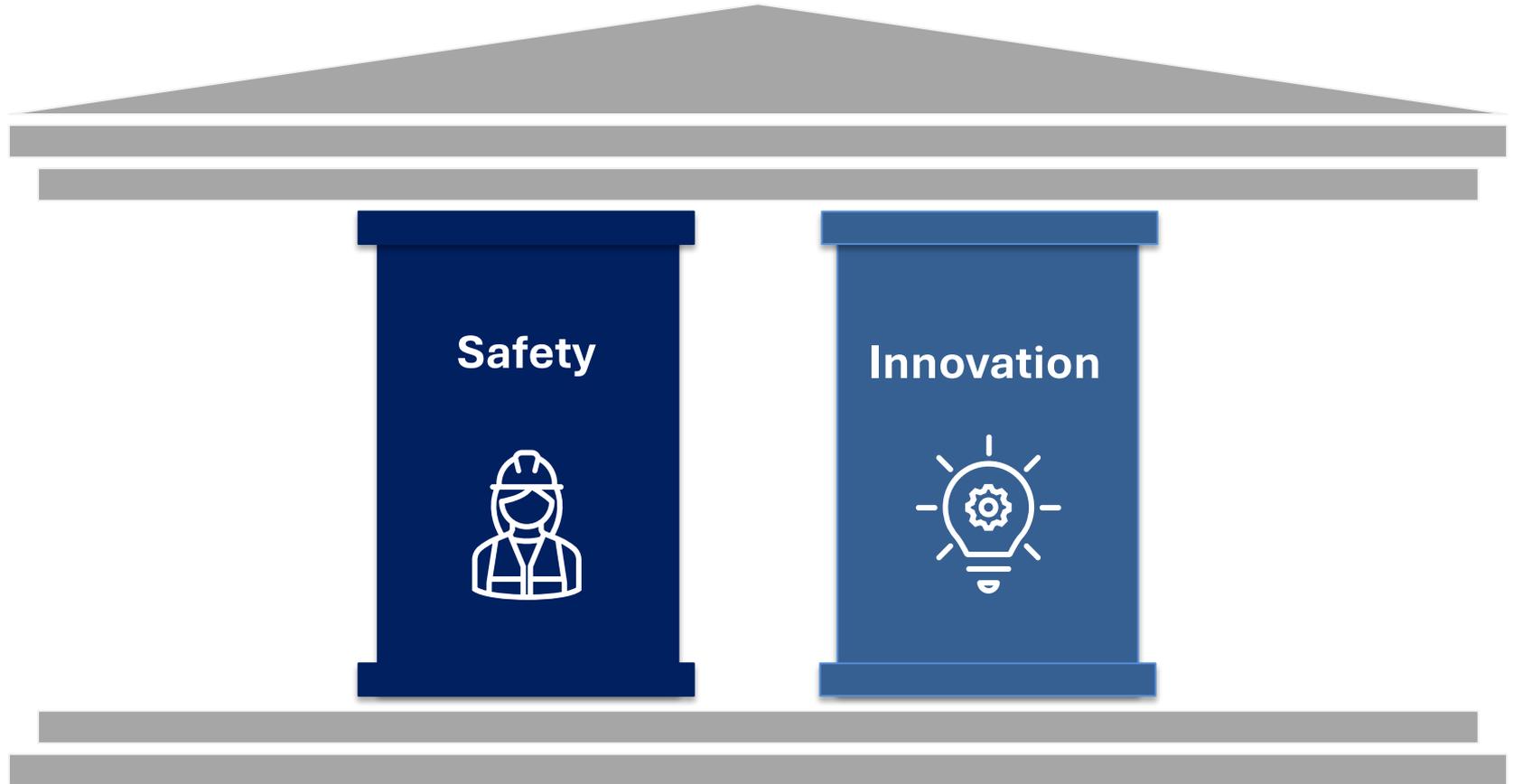


CDRH Vision

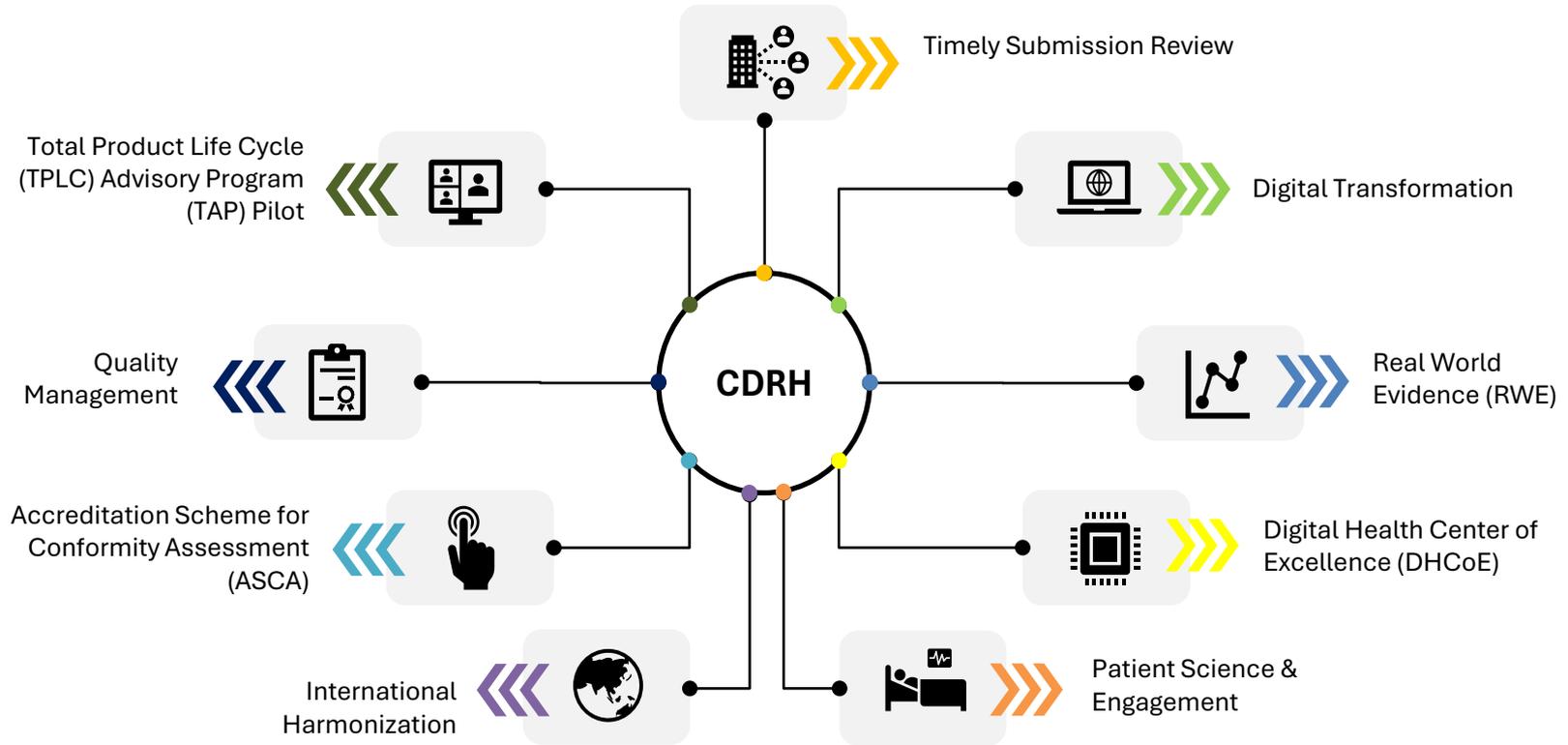
Patients in the U.S. have access **to high-quality, safe, and effective** medical devices of public health importance first in the world*

**Our vision does not signal a competition with other countries - but rather provides a metric for timely patient access to devices that meet FDA's standards.*

CDRH Core Pillars



MDUFA V Supported Programs





Key MDUFA V Supported Programs

Submission Type	Action	Review-Time Goal	FY23 Current Performance	FY24 Current Performance	FY25 Current Performance
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	Substantive Interaction	95% in 90 calendar days	Goal met	Goal met	Currently meeting goal; final performance TBD
	Decision with No Advisory Committee Input	90% in 180 FDA days	Goal met	Currently meeting goal; final performance TBD	N/A
180-Day PMA Supplements	Substantive Interaction	95% in 90 calendar days	Goal met	Goal met	Currently missing goal; final performance TBD
	Decision	95% in 180 FDA days	Goal met	Currently meeting goal; final performance TBD	Currently meeting goal; final performance TBD
Real-Time PMA Supplements	Decision	95% in 90 FDA days	Goal met	Goal met	Currently meeting goal; final performance TBD
De Novo Classification Requests	Decision	70-90% in 150 FDA days	Goal met	Currently meeting goal; final performance TBD	Currently meeting goal; final performance TBD
510(k) Premarket Notifications	Substantive Interaction	95% in 60 calendar days	Goal met	Currently meeting goal; final performance TBD	Currently meeting goal; final performance TBD
	Decision	95% in 90 FDA days	Goal met	Currently meeting goal; final performance TBD	Currently meeting goal; final performance TBD
Pre-Submissions	Provide Written Feedback	75-90% in 70 calendar days (or 5 days prior to meeting)	Goal met	Goal met	Currently meeting goal; final performance TBD

-  Goal met
-  Currently meeting goal; final performance TBD
-  Currently missing goal; final performance TBD

Real-World Evidence Draft Guidance

Expanded Sections



- General Considerations for the use of RWE
- General expectations for relevance and reliability assessment
- Appendix: List of five generalized examples of RWE use to support regulatory decision making

Contains Nonbinding Recommendations
Draft – Not for Implementation

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

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New Sections



- Application of RWD from devices with EUAs
- Considerations for Methodologies for Collection and Analysis of RWD
- Documentation for FDA Review
- Appendix: Recommended Elements for Documentation and FDA Review



TAP Pilot Update



Up to 15 total devices
• Cardiovascular

Up to 60 total devices
• Cardiovascular
• Neurological
• Physical Medicine

Up to 125 total devices
• Cardiovascular
• Neurological
• Physical Medicine
• Ophthalmic
• Radiological
• Orthopedic (from 1/2025)
93 enrolled

Up to 225 total devices
• Expansion into additional clinical areas to be determined
• Safer Technologies Program (STeP) devices in participating clinical areas

Up to 325 total devices
• Expansion into additional clinical areas to be determined



Engage in a teleconference within 14 days for 90% of requests for interaction



Written feedback on biocompatibility and sterility topics within 21 days for 90% of requests



Written feedback on all other requested topics within 40 days for 90% of requests

100% of quantitative performance metrics met

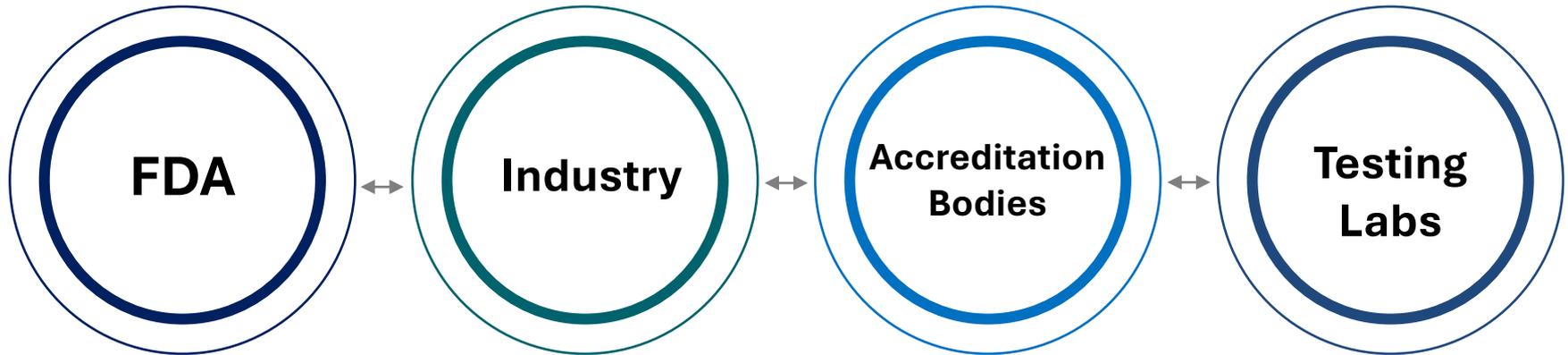
Digital Health & AI

1000+ FDA authorized AI/ML-enabled medical devices

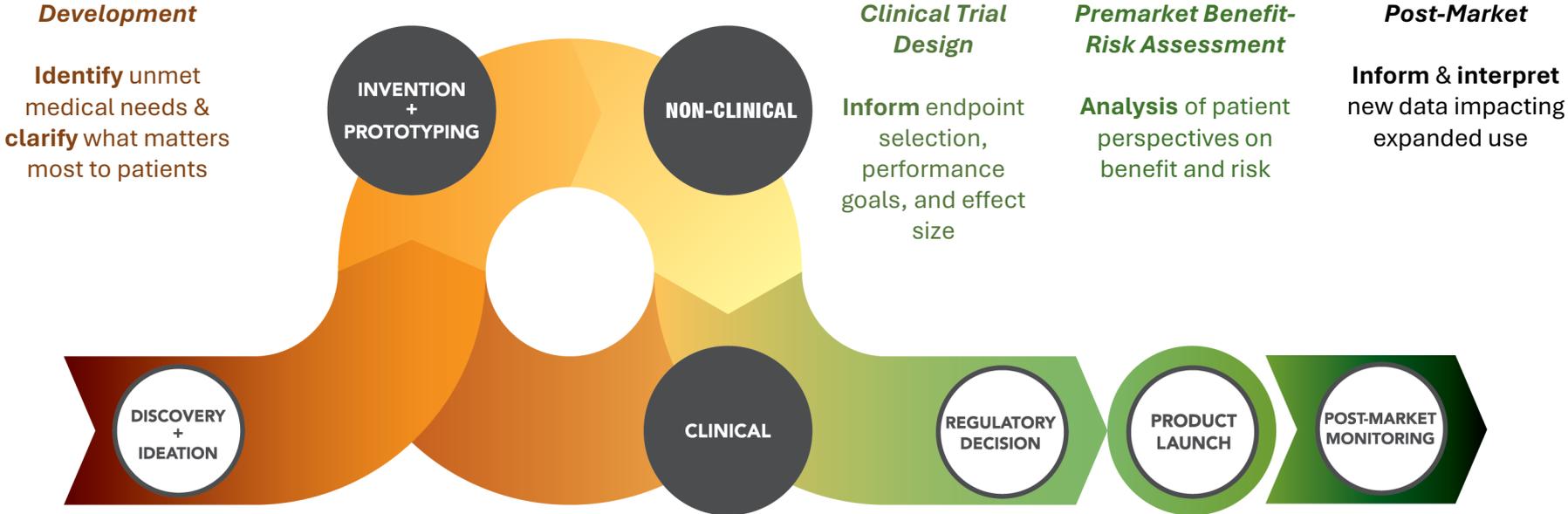
Milestones

2019	2020	2021	2022	2023	2024 / 2025
<ul style="list-style-type: none"> Published AI/ML-SaMD Discussion Paper First joined Collaborative Community related to AI/ML 	<ul style="list-style-type: none"> Public Workshop on AI/ML in Radiological Imaging Patient Engagement Advisory Committee Meeting on Patient Trust in AI/ML Devices 	<ul style="list-style-type: none"> Posted List of Currently Authorized AI/ML Devices Published AI/ML Medical Device Software Action Plan Public Workshop on Transparency of AI/ML Devices Published Good Machine Learning Practice Principles 	<p>List Updated</p> <ul style="list-style-type: none"> Contributed to IMDRF's Key Terms & Definitions: Machine Learning Enabled Medical Devices Published Clinical Decision Support (CDS) Final Guidance Recognized new Consensus Standard on AI/ML Published Digital Health Policy Navigator 	<p>List Updated</p> <ul style="list-style-type: none"> Published Predetermined Change Control Plan for AI/ML Devices Draft Guidance Announced formation of Digital Health Advisory Committee Published PCCP Guiding Principles 	<p>List Updated</p> <ul style="list-style-type: none"> Published AI & Medical Products paper on how CBER, CDER, CDRH, and OCP are working together Developed AI and Medical Products page centralizing AI resources across FDA.gov NPJ journal article on Transparency in AI/ML-enabled devices Published AI Glossary Published w/MHRA & HC ML Transparency Principles Document

ASCA



Patient-Centered Development & Evaluation



MDUFA V Transparency

International Harmonization



- Publish strategic plan
- Publish annual assessments of activities and progress related to the strategic plan

Quality Management Audits



- Conduct audits on key programs; publish annual reports with findings and corrective actions
- Conduct annual audits of deficiency letters and review results with Industry

Financial Reporting



- Maintain 5-year financial plan with up-to-date information on hiring, costs per FTE, balances in reserves, and funding for certain programs
- Annual financial report to Congress

Performance Reporting



- Quarterly reports of progress meeting performance goals published on website and discussed in meetings with industry
- Annual performance report to Congress

Independent Assessments



- MDUFA workforce metrics assessment
- Review process management assessment
- TPLC Advisory Program (TAP) pilot assessment

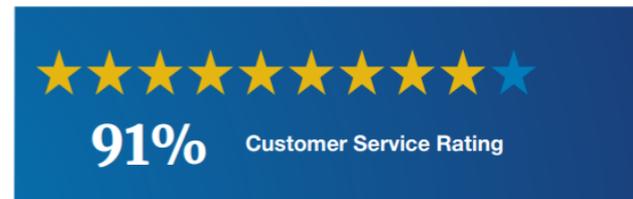
CDRH By the Numbers: A Snapshot from 2024



Safety-Related Communications



Device Innovation





CDRH Vision

Patients in the U.S. have high-quality, safe, and effective medical devices of public health importance **first in the world**

Industry Perspective

Medical Device Manufacturers Association

Mark Leahey, J.D., M.B.A

Industry Perspective

AdvaMed

Janet Trunzo, M.S.

Zach Rothstein, J.D. (AdvaMedDx)

Patrick Hope, J.D., M.A. (AdvaMed Medical Imaging)

Patient & Consumer Perspective

Annie Kennedy, B.S.

EveryLife Foundation for Rare Diseases

Patient & Consumer Perspective

Kelly Close, M.B.A

diaTribe Foundation



Perspectives to consider for MDUFA

- Where possible, **use technology to increase the predictability and quality of regulatory reviews.** Don't leave regulators in the dark while the rest of the world uses AI to our advantage.
- **Create a better evidence model of regulatory quality and effectiveness.** The industry and FDA should not have to rely on a super-quick, under-resourced, novel independent assessment every five years. Instead, build the evidence framework for MDUFA directly into the fabric of the FDA data systems and processes.



Perspectives to consider for MDUFA

- **Have a robust decision analysis program**, to help improve the quality of regulatory decisions systematically over time.
- **Promote FDA programs, such as the MDDT Program** – this is the only known regulatory innovation mechanism that could scale.
- **Create complete models of patient value** - including disease burden, safety, efficacy - that can serve as references for endpoint measurement. Too often, the “total universe of what matters” to a patient population is unknown.

Patient & Consumer Perspective

Diana Zuckerman, Ph.D.

National Center for Health Research



MDUFA V Focus: What FDA Must Do to Deserve User Fees

- “FDA will do ___” is stated 200 times in the Commitment Letter
- Is Industry being regulated or is FDA being regulated? What should FDA negotiate for on behalf of patients?
- Performance data should also be based on accomplishments most important to patients, pre- and post-market.
- Since pre-market review rarely includes clinical evidence of safety or effectiveness, user fees should help pay for timely post-market reviews.



How can MDUFA Improve Performance?

- Are clinical studies too small or short-term? Are safety or effectiveness data analyzed for male and female patients of different ages?
- Are DTC ads, detailing activities, or ads to doctors directly or indirectly promoting inappropriate off label use?
- Support FDA staff to create Patient Booklets, Informed Consent Checklists, etc.
- Support postmarket surveillance, “Dear Doctor” letters, warnings to patients, recall campaigns.

Patient & Consumer Perspective

Katie Sale, B.A.

American Brain Coalition





Patient & Consumer Perspective

Mark Stewart, Ph.D.

Friends of Cancer Research

Patient & Consumer Perspective

Panel Discussion

Lunch Break

Please return by 1:30PM

Scientific, Academic, & Health Care Professional Perspectives

Zach Hochstetler, M.B.A.

American Medical Association

Scientific, Academic, & Health Care Professional Perspectives

Natalie Torentinos, M.P.S.

Children's Hospital Association

Scientific, Academic, & Health Care Professional Perspectives

Panel Discussion

Open Public Comment Period

Isabella Xu, M.P.H.

Center for Science in the Public Interest

A portrait of a young woman with long, dark hair, wearing a dark jacket. She is looking directly at the camera with a neutral expression. The background is a solid teal color with a faint, stylized graphic of a plant with large leaves on the left side.

Isabella Xu

Open Public Comment Period

Alexander Naum, J.D.

Generation Patient

Open Public Comment Period

Jason Spiegler

NMI Skyspace-US

Open Public Comment Period

Tess Robertson-Neel, M.P.H.

Patient, Consumer, and Public Health Coalition

Your Feedback



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Email Address:

MDUFAVIREauthorization@fda.hhs.gov

Closing Remarks

Owen Faris, Ph.D.

*Deputy Center Director for Regulatory Operations
Center for Devices and Radiological Health*

