FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Returning to the New Normal in the Face of Evolving Challenges: Update from CDRH

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Medical Devices Include a Broad Range of Technologies

- OTC hearing aids
- Blood glucose monitors
- Personal protective equipment (PPE)
- Wearable sensors
- Next generation sequencing tests
- Heart valves
- AI/ML
- Robotics

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.

CDRH BY THE NUMBERS IN 2022

90%

CUSTOMER SERVICE RATING

1,922
DEDICATED CDRHERS

238,000
REGULATED DEVICES

18,800
SUMISSIONS RECEIVED

27,000
DEVICE MANUFACTURING FIRMS

55
NEW OR UPDATED GUIDANCES

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

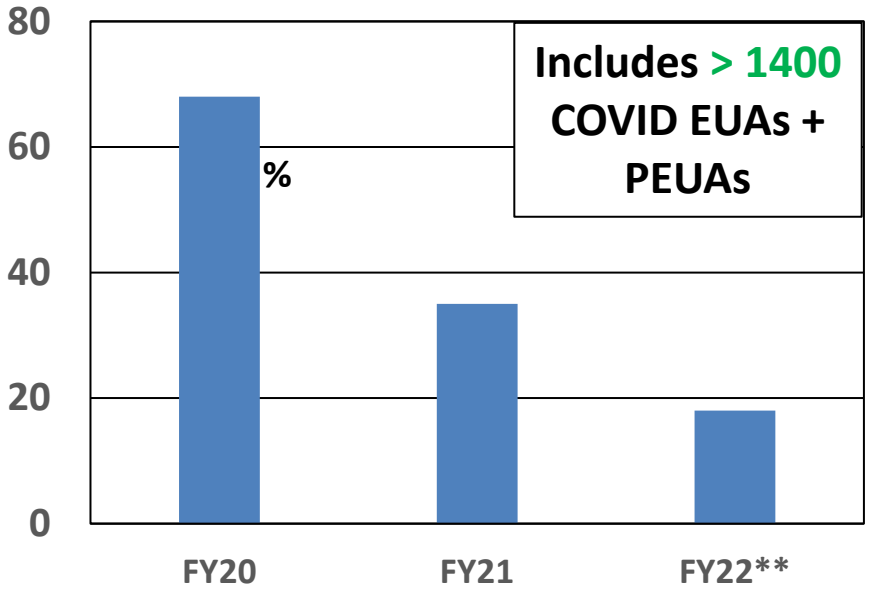
714 TWEETS

54 FACEBOOK POSTS

194 LINKEDIN POSTS

Unprecedented Workload from COVID-19 Pandemic

Increase in Submission Volume Compared with FY19*



* Includes 510(k), De Novo, Qsubs, PMA (original, panel track, 180 day, and real-time), EUA and PreEUA
** Through 10/17/22

CDRH and COVID-19 by the numbers

CDRH has received submissions for 4217 EUAs and 2989 pre-EUAs since January 2020

CDRH has issued EUAs or provided traditional marketing authorization to over 2800 devices for COVID-19:

- Of these, 956 are device EUAs (15 times more than all previous PHEs combined)

- Of the EUAs, over 500 are for COVID-19 tests including 35 OTC tests

Top 10 Transition Tips

1. Read our final guidance
2. Understand the transition plan
3. Think about your transition plan NOW!
4. Do a gap analysis between pre- and post-transition regulatory expectations
5. Describe product changes since the last cleared/approved device
6. Make a decision
7. Make smart use of pre-submission program
8. Use eSTAR
9. Have a transition implementation plan
10. Don’t wait to submit

CDRH - Lessons Learned from COVID

Agile Organization

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Proactive Engagement

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Flexible Regulatory Framework

COVID-19 Medical Device Shortages

CDRH has received shortage signals for 455 product categories
Our work mitigated 346 of those signals

Testing Supplies and Consumables


Swabs & Transport Media


Blood Collection Tubes


Pipettes


Laboratory Testing Supplies


Laboratory Reagents

Test Kits

Personal Protective Devices & Ventilation


Ventilators


Respirators


Gloves

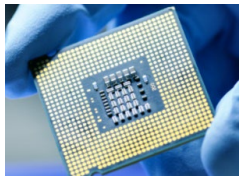

Surgical Gowns


Surgical Masks


Examination Gown

Cross-Cutting Examples


Resin


Semiconductors

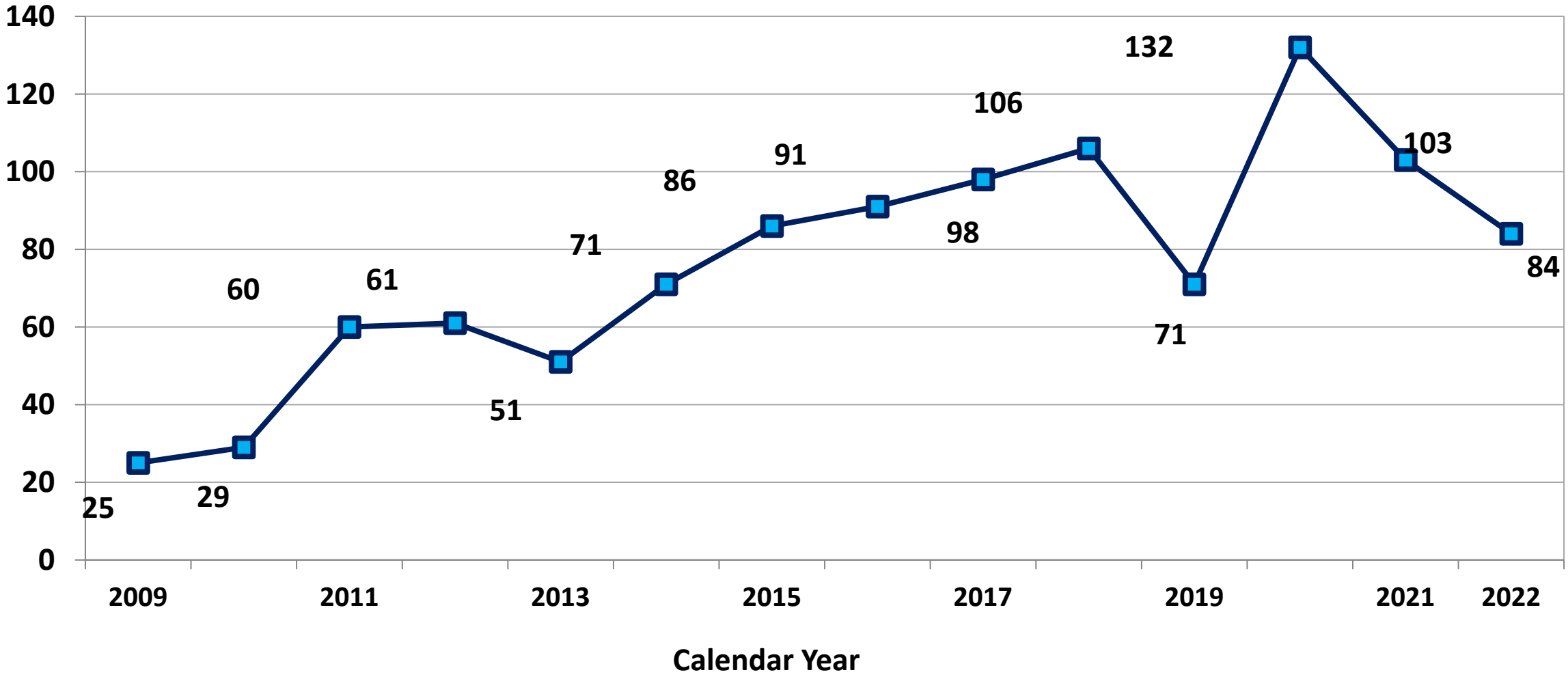

Ethylene Oxide


Paper (e.g., labels)


Silicone

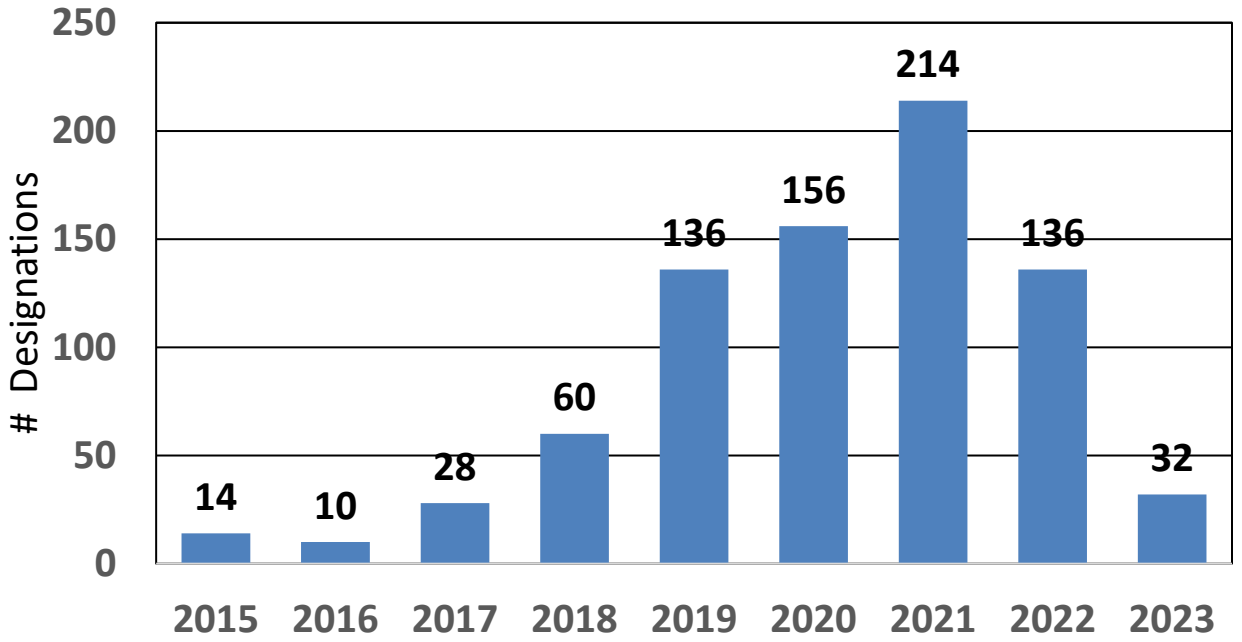
Sustained Increase in Novel Device Authorizations*

> 3-fold Increase in # of Novel Device Authorizations



* Novel devices include original PMAs, panel track supplement PMAs, De Novos, HDEs, breakthrough 510(k)s, and specific EUAs deemed novel.

Breakthrough Devices Program



- Interactive & Timely Communication
- Pre-Postmarket Balance
- Flexible Clinical Study Design
- Senior Management Engagement
- Priority Review

786
Designated Devices

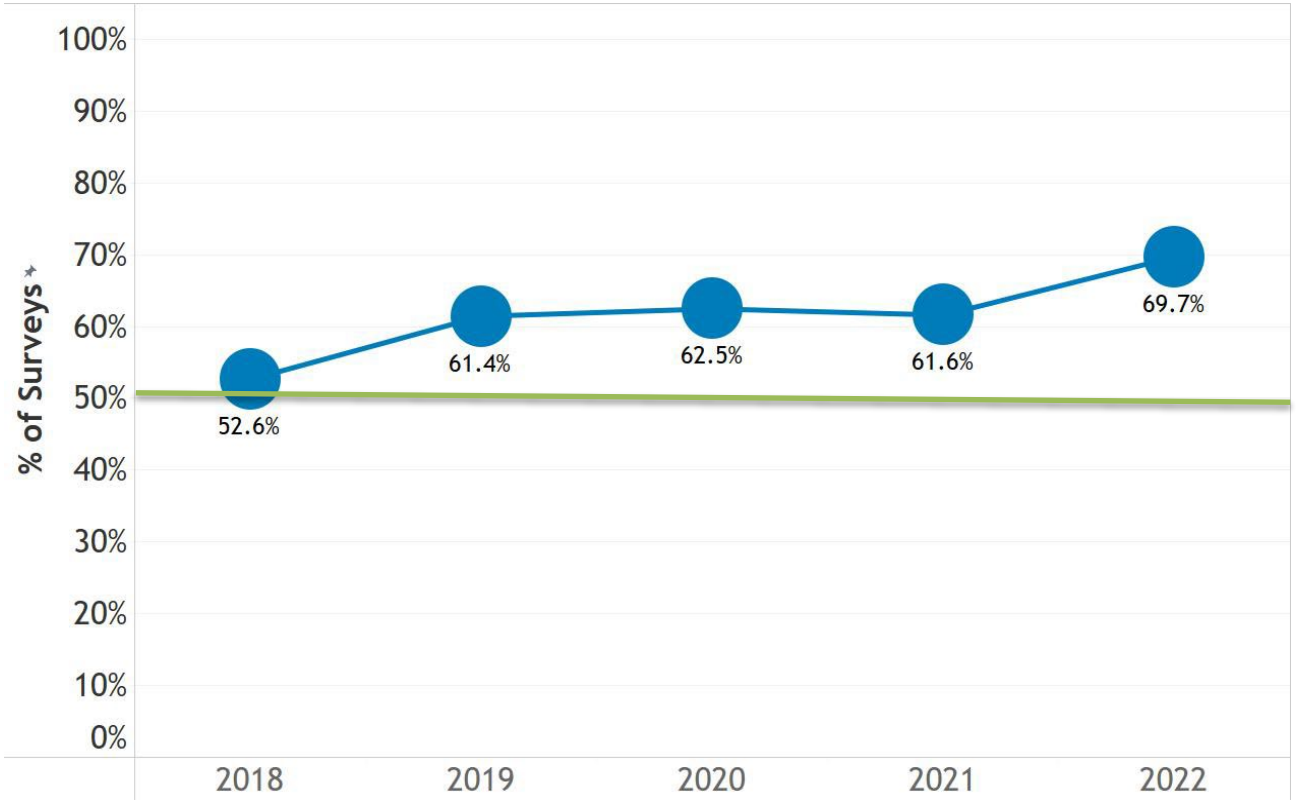
65
Marketing Authorizations
20 PMAs
24 510(k)s
21 De Novos

* Through 3/31/23

2018-2020 Strategic Priorities Goal for Novel Technologies

Measure of Success - By December 31, 2020, more than 50 percent of manufacturers of novel technologies for the U.S. market intend to bring their devices to the U.S. first or in parallel with other major markets.

Change Hearts and Minds



CDRH 2022-2025 Strategic Priorities

Measures of Success

- By December 31, 2025, more than **90 percent** of manufacturers of novel technologies for the U.S. market **intend** to bring their devices to the U.S. first or in parallel with other major markets.

- By December 31, 2025, more than **50 percent** of manufacturers of newly authorized novel technologies for the U.S. market **brought** their devices to the U.S. first or in parallel with other major markets.

- By December 31, 2025, FDA identifies and **acts on significant safety signals** related to medical devices marketed in the U.S. and other major markets first or in coordination with regulatory agencies of other major markets more than **50 percent** of the time.

MDUFA Program History

MDUFA I - MDUFMA (FY2003-FY2007)

Authorized FDA to collect user fees for the review of premarket submissions. Enacted to provide additional resources to an under resourced medical device program.

MDUFA II - FDA Ammendments Act (FY2008-FY2012)

Reauthorized user fee collections and established tiered performance goals for 510(k) and PMA.

MDUFA III - FDASIA (FY2013-FY2017)

Reauthorized user fee collections and increased resources for medical device programs. Created more aggressive performance goals and introduced interim performance milestones (RTA, SI).

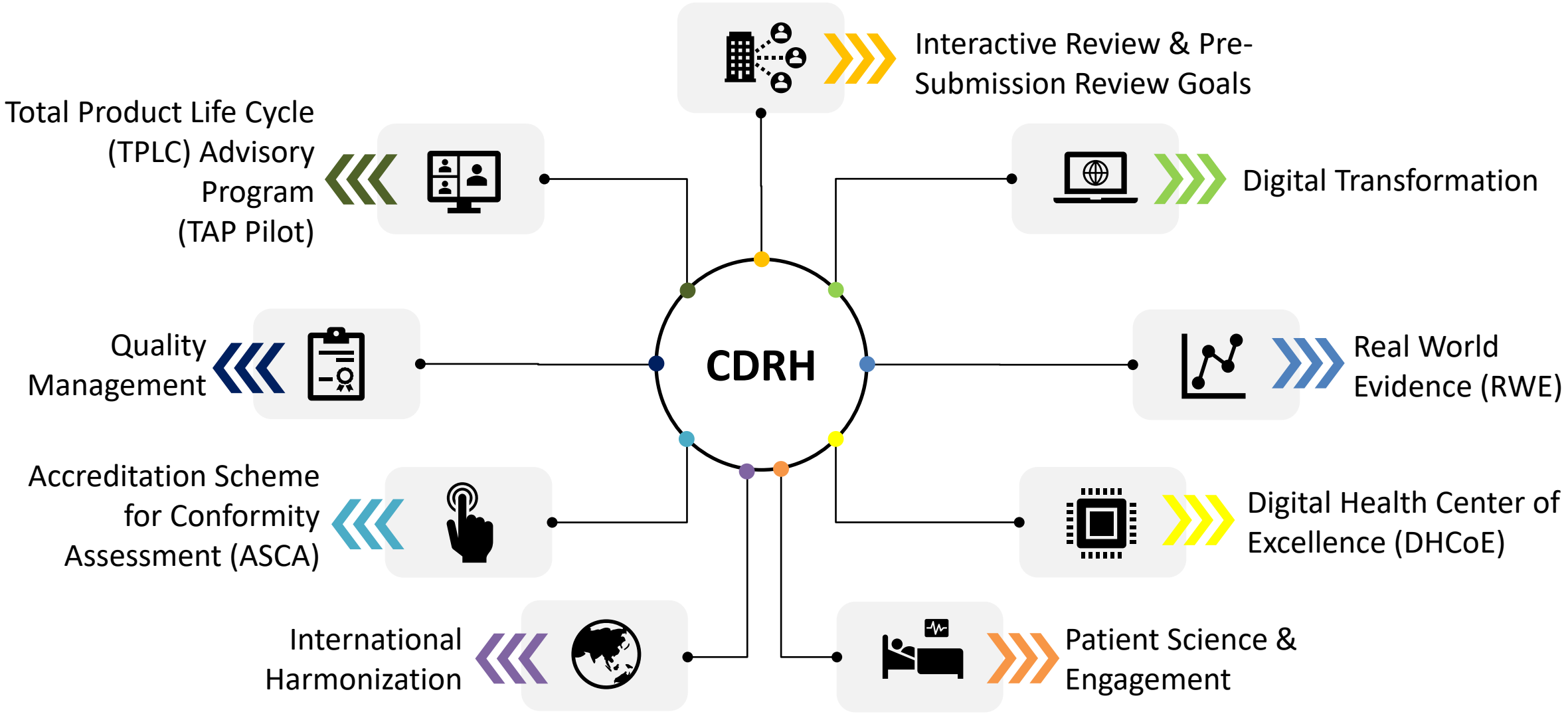
MDUFA IV - FDARA (FY2018-FY2022)

Reauthorized user fee collections, increased resources, created more aggressive performance goals for 510(k) and PMA, introduced new performance goals for De Novo and Pre-Sub. Support for NEST, digital health, ASCA Pilot, and patient engagement.

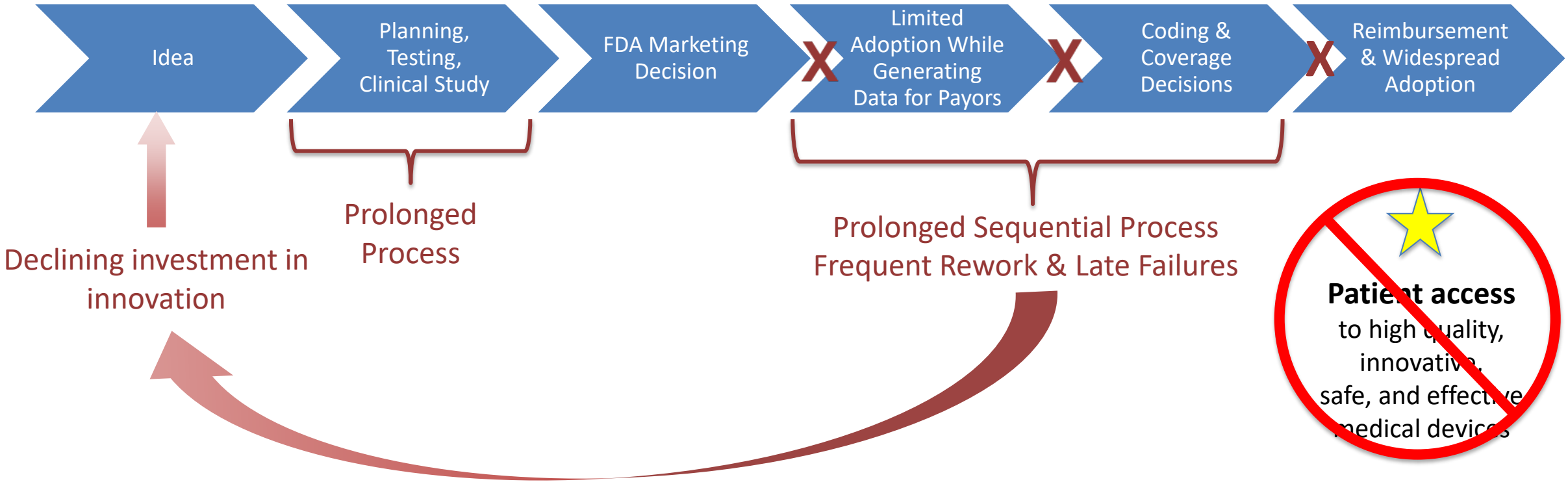
MDUFA V - FDASLA (FY2023-FY2027)

Reauthorizes user fee collections, increases resources, improves goals for PMA and 510(k) Total Time to Decision, Pre-Sub and De Novo, introduces new goal structure with “add-on” payments, support global harmonization, creates TAP Pilot.

MDUFA V Supported Programs



Patient Access to Innovation is Blocked by not Understanding Evidence Needs of Non-FDA Stakeholders Critical for Commercialization

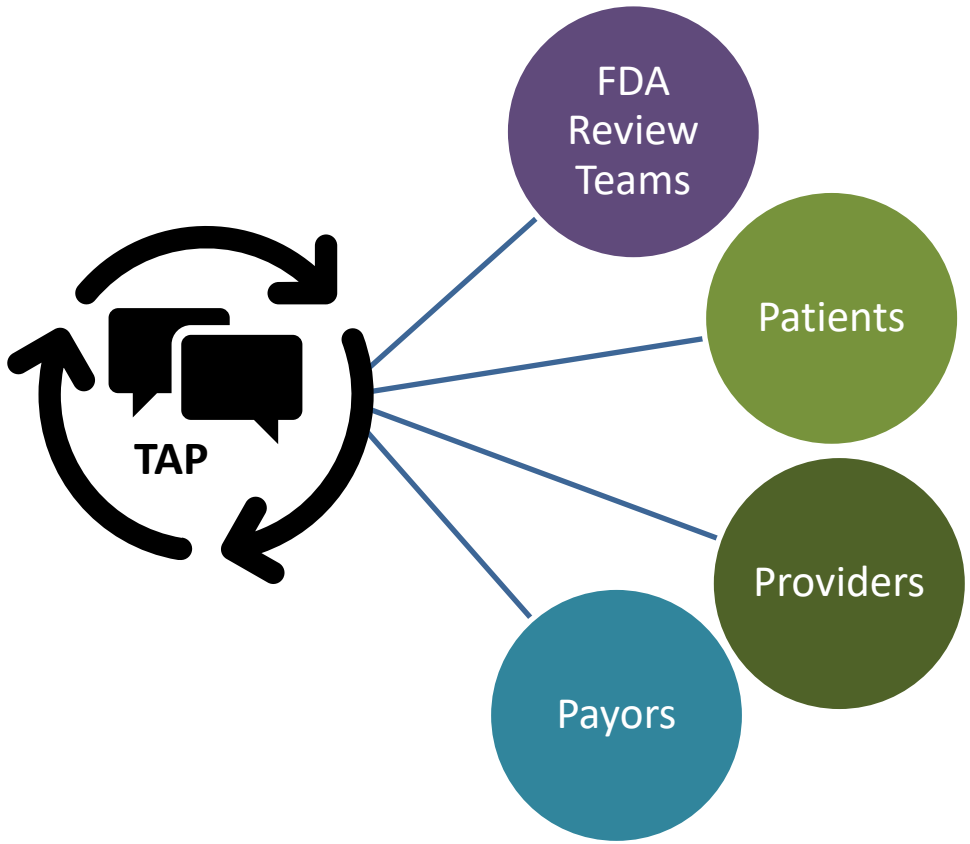


Poor inputs/planning = high risk/cost = low predictability/access

In MDUFA V, We Address the Problem w/ the TPLC Advisory Program (TAP)

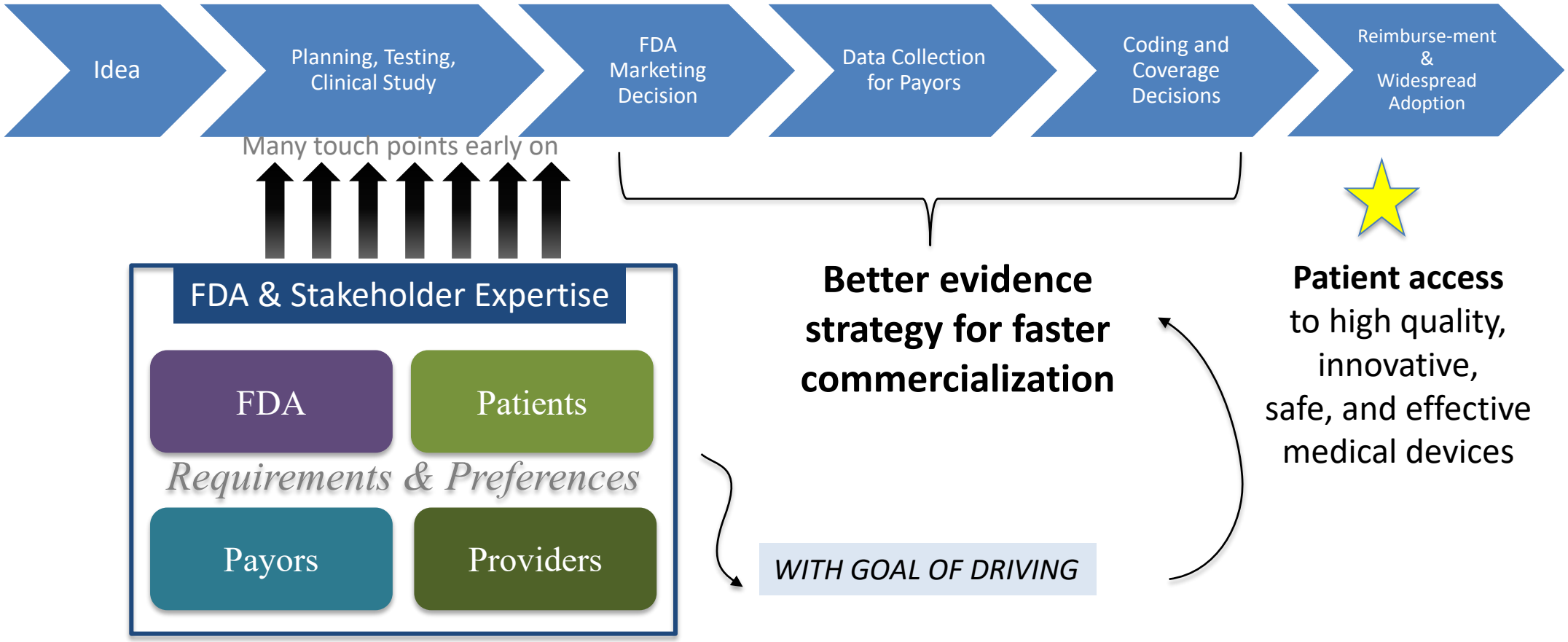
TPLC Advisory Program (TAP)

- **TAP Advisors**, a new team of experts who provide dynamic, strategic advice actively coordinated with FDA review teams and across the MedTech ecosystem
- **Rapid-response** capacity to engage FDA reviewers and stakeholder experts across full spectrum of device types



Early, Frequent, Coordinated Stakeholder Interaction Speeds Patient Access

A shorter, happier journey



CDRH 2022-2025 Strategic Priority: Advance Health Equity

Reduce Barriers
and increase opportunities for participation by diverse populations in evidence generation

Support Innovation
of novel technologies that address health equity gaps

Facilitate Availability
of and access to existing and novel home-use medical technologies for all populations

Empower People
to make informed decisions regarding their healthcare

CDRH's Digital Health Center of Excellence

is advancing health care by fostering responsible and high-quality digital health innovation

Digital technology is the linchpin for transforming integrated healthcare delivery, bringing quality healthcare to underserved populations by moving healthcare to the home setting, and reducing costs

CDRH has authorized over 500 AI/ML-enabled devices and we have been test-driving innovative regulatory approaches, such as precertification

Digital therapy device to reduce sleep disturbance for psychiatric conditions

Digital therapy device for Attention Deficit Hyperactivity Disorder

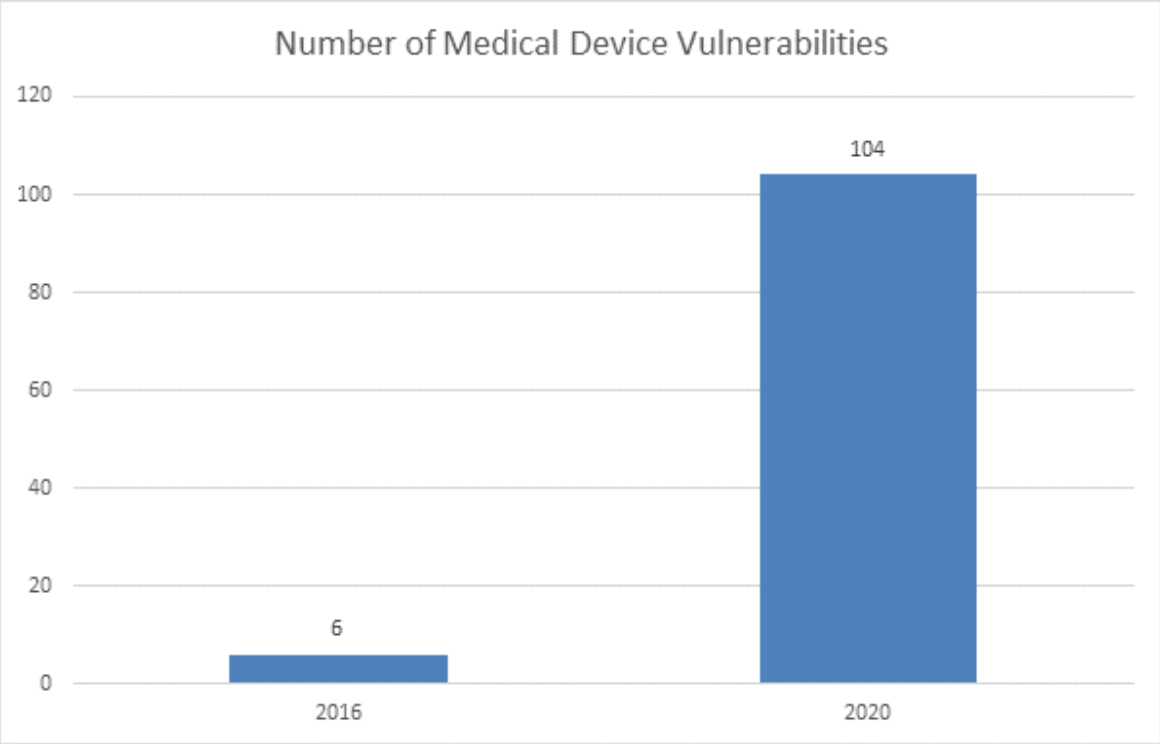
Electrocardiograph software for over-the-counter use

Virtual reality behavioral therapy device for pain relief

Self-fitting over-the-counter hearing aids

Number of Cybersecurity Vulnerabilities Discovered in Marketed Devices is Rising

There was a 17-fold increase in device-related vulnerabilities from 2016 to 2020:



*Data pulled from Cybersecurity and Infrastructure Security Agency Alerts

Including:

2017: Cybersecurity vulnerabilities identified in St Jude Medical's implantable cardiac devices and Merlin@home transmitter: FDA Safety Communication

2017: Cybersecurity updates affecting Medtronic implantable cardiac device programmers: FDA Safety Communication

2019: FDA informs patients, providers and manufacturers about potential cybersecurity vulnerabilities for connected medical devices and healthcare networks that use certain communication software

2020: SweynTooth cybersecurity vulnerabilities may affect certain medical devices: FDA Safety Communication

2021: BadAlloc vulnerability affecting Blackberry QNX RTOS

2022: Illumina cybersecurity vulnerability may present risks for patient results and customer networks: Letter to healthcare providers

Statutory Red Tape

- 47-year old statutory framework is no longer fit for purpose for modern day medical devices, such as AI, and is a barrier to high-quality, lower cost healthcare in the US

- The pandemic taught us what we need to do but will we learn from our experiences?

- Solution is to remove the red tape: Establish a *voluntary alternative pathway* (VAP) as a new, second option in addition to traditional premarket pathways – still meet the US standard of RASE and the least burdensome principle but provide flexibility in how to meet the US standard that is tailored to the technology

CDRH - Lessons Learned from COVID

Agile Organization – CDRH Strategic Priorities

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Proactive Engagement – MDUFA V TAP

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Flexible Regulatory Framework – VAP