Overview of FDA Regulation of Medical Devices & Digital Health

M. Jason Brooke, MSE, JD, CSQE

Shelby Buettner, JD, MPA

November 9, 2021

Agenda

- FDA Legal and Regulatory Framework for Medical Devices
- New Paradigm for Software as a Medical Device
- Is the Software an FDA-Regulated Medical Device?

FDA U.S. FOOD & DRUG ADMINISTRATION

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What is Digital Health?

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Digital Health Center of Excellence

About the Digital Health Center of Excellence

Digital Health Center of Excellence Services

Ask a Question About Digital Health Regulatory Policies

Jobs in the Digital Health Center of Excellence

The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

From mobile medical apps and software that support the clinical decisions doctors make every day to artificial intelligence and machine learning, digital technology has been driving a revolution in health care. Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual.

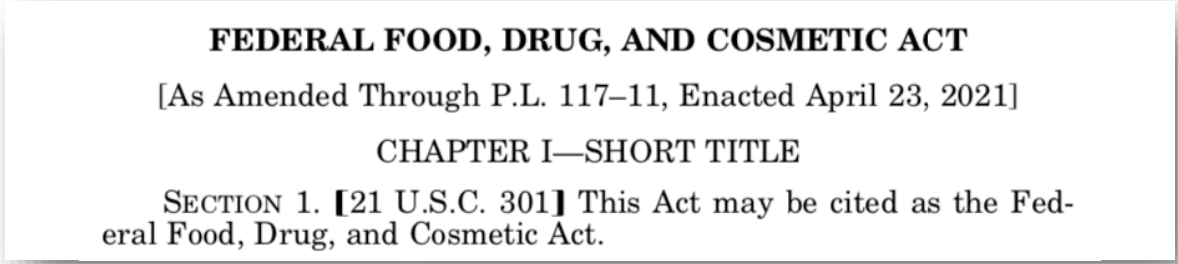
Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.

Content current as of:
09/22/2020

Regulated Product(s)
Medical Devices

FDA Legal & Regulatory Framework for Medical Devices

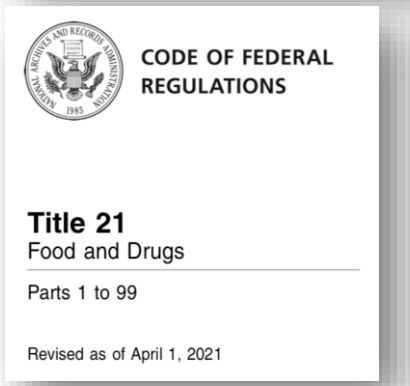
- Statute
  - Federal Food, Drug, and Cosmetic Act
- Regulations
  - Title 21 of the Code of Federal Regulations (CFR)
- Guidance Documents
  - Nonbinding recommendations
  - "Good Guidance Practices" (21 CFR 10.115)
- Other Resources
  - Databases
  - Programs and Pilots
  - Action plans
  - Proposed regulatory framework documents
  - Discussion papers and requests for feedback
  - Guiding principles documents
  - Reports
  - Safety communications


FEDERAL FOOD, DRUG, AND COSMETIC ACT

[As Amended Through P.L. 117–11, Enacted April 23, 2021]

CHAPTER I—SHORT TITLE

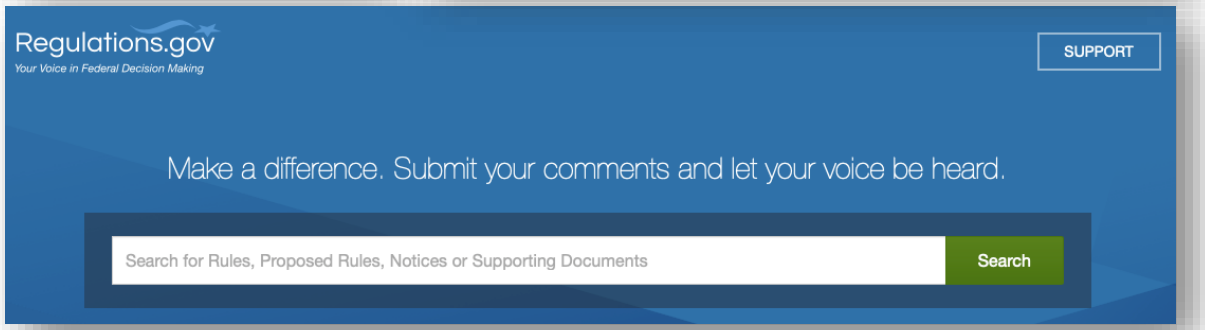
SECTION 1. [21 U.S.C. 301] This Act may be cited as the Federal Food, Drug, and Cosmetic Act.


CODE OF FEDERAL REGULATIONS

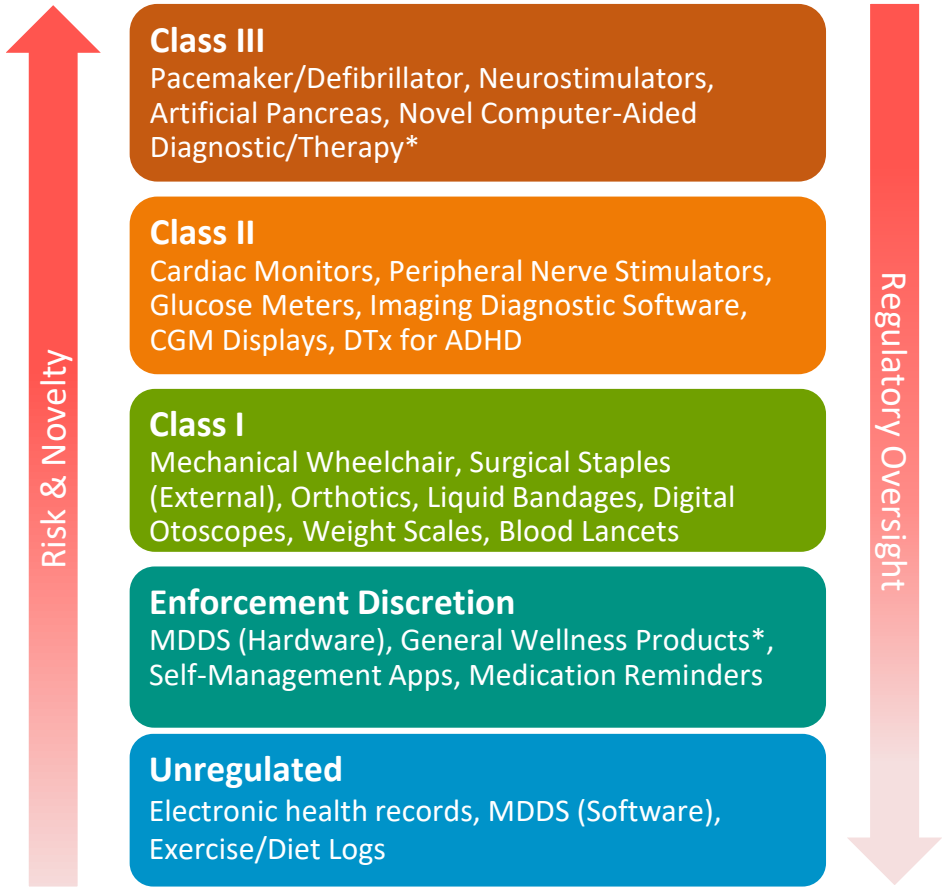
Title 21
Food and Drugs

Parts 1 to 99

Revised as of April 1, 2021



FDA Legal & Regulatory Framework for Medical Devices



Section 201(h) defines "device"

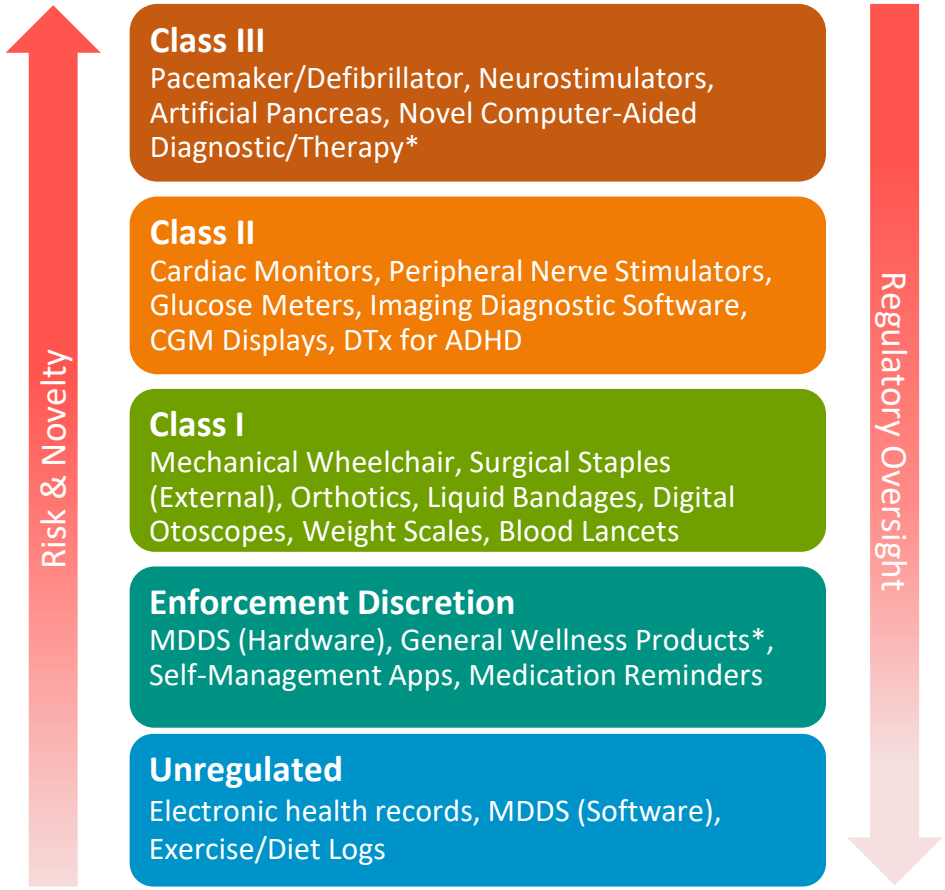
Generally - any product, component, or accessory, that is:

1) Intended by its manufacturer
    a) for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or medical condition; or
    b) to affect the structure or any function of the body; and
2) Does not achieve its primary intended purposes through chemical action

Section 520(o) excludes software from the definition of device that:

1) Is intended for administrative support of a healthcare facility (e.g., processing and maintenance of claims or billing information, appointment schedules, health benefit eligibility, and laboratory workflow)
2) Is intended for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
3) Is intended to serve as an electronic patient record
4) Is a medical device data system…

FDA Legal & Regulatory Framework for Medical Devices



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CONTINUED - Section 520(o) excludes software from the definition of device that:

5) a) Is not intended to acquire, process, or analyze a medical image or device signal or pattern;

   b) Is intended for displaying, analyzing, or printing medical information;

   c) Is intended for supporting or providing recommendations to a HCP about prevention, diagnosis, or treatment; and

   d) Is intended to enable HCP to independently review the basis for recommendations and, hence, is not intended for HCP to primarily rely on the recommendations.

Quality System Overview

- Medical devices (including SaMD) must be developed within a Quality System that governs all activities of product development, post-market surveillance, and corporate governance related to product quality
- An organizational structure must be established and qualified personnel must be in place to support development and maintenance of the Quality System

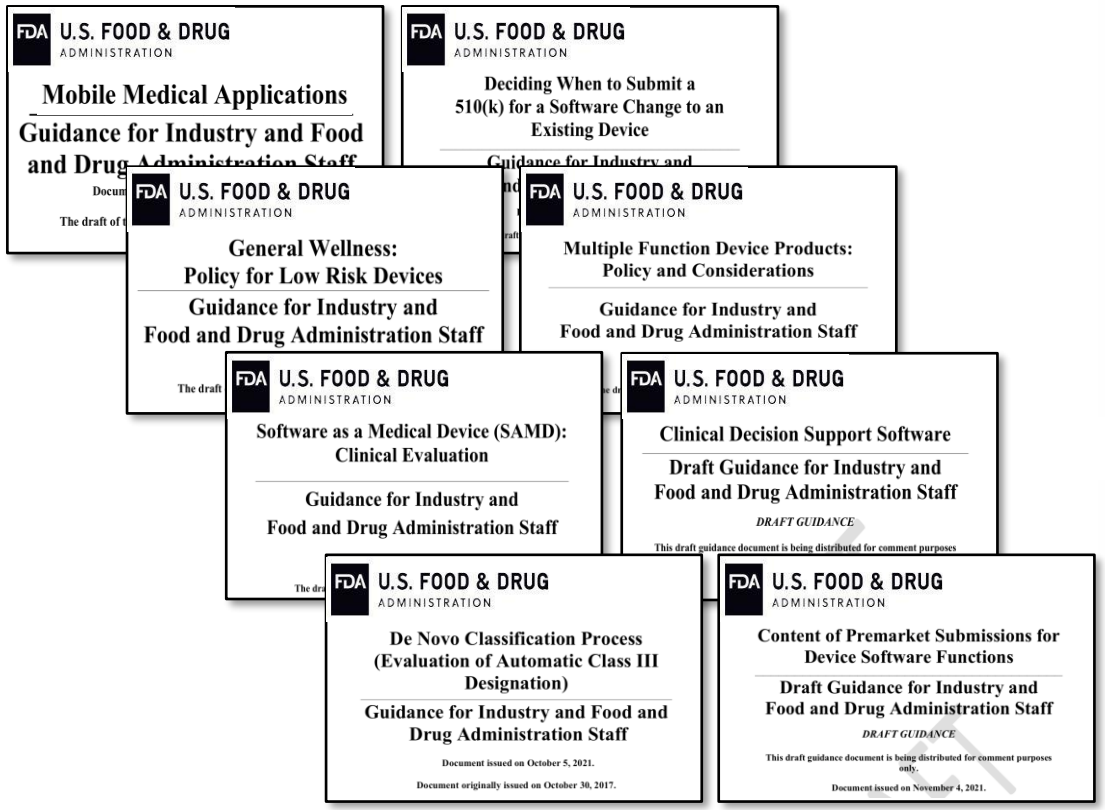
21 CFR Part	Title
1	General Enforcement
7	General Recall Enforcement
11	Electronic Records & Signatures
50	Protection of Human Subjects
801	Labeling
803	Medical Device Reporting
806	Reports of Corrections and Removals
807	Registration & Listing
810	Medical Device Recall Authority
812	Investigational Device Exemptions
820	**Quality System Regulation**
830	Unique Device Identification

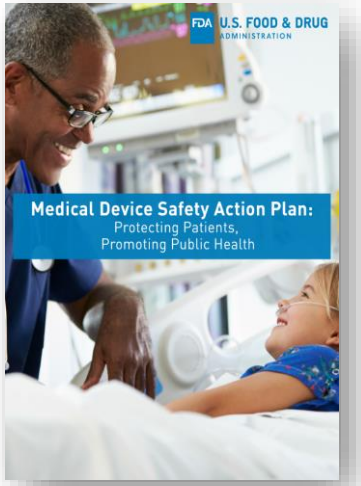
Part 820 applies to almost all medical device manufacturers

- Any person who designs, manufacturers, fabricates, assembles, or processes a finished device (including spec developers)
- Exemptions for some Class I devices and IDE devices

The New Paradigm for Software as a Medical Device

Beginning in ~2010, the FDA embarked on a deregulatory journey in regards to digital health technologies





Shifting to a Total Product Lifecycle Approach

Post-Market Oversight

Pre-Market Review

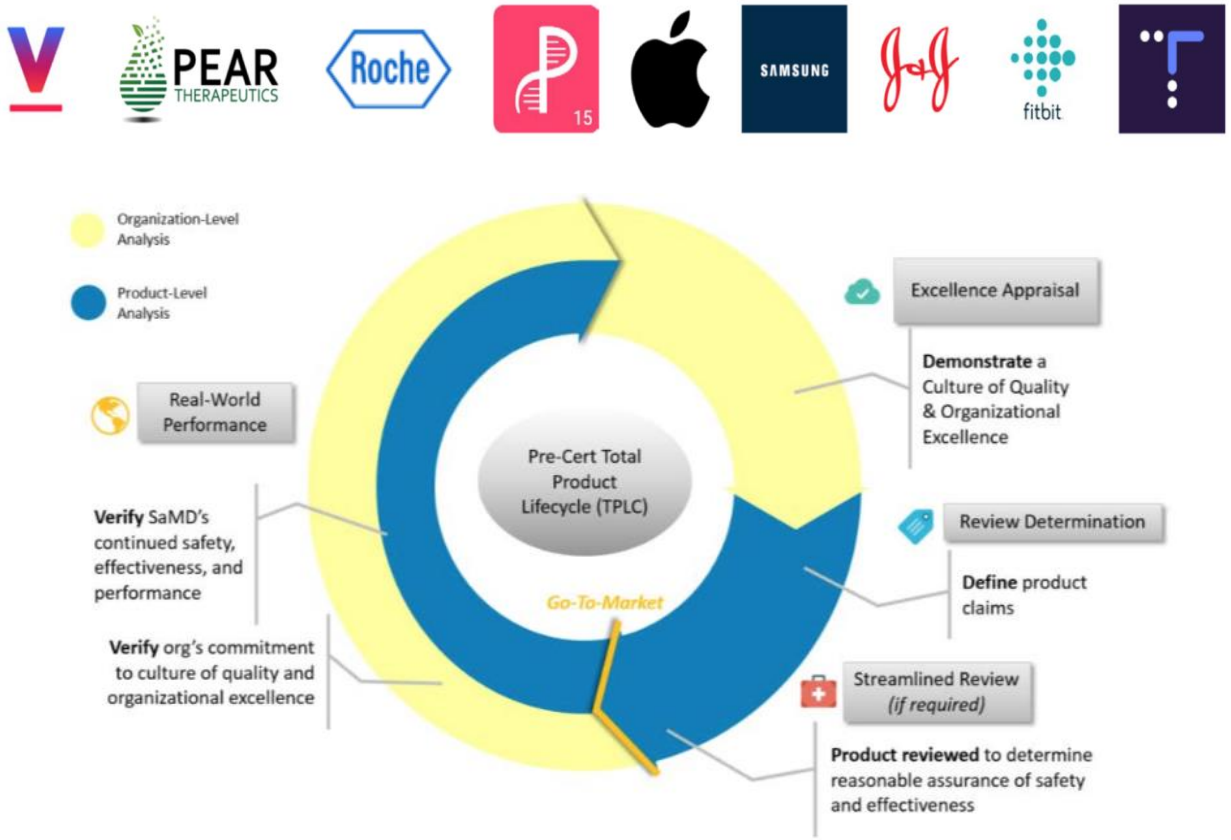
Reimagining digital health product oversight

- "FDA intends to develop a precertification program that could **replace the need for a premarket submission** for certain products and allow for decreased submission content and/or faster review of the marketing submission for other products."
- "[C]ollect real-world data postmarket that might be used . . . to affirm the regulatory status of the product, as well as to support new and evolving product functions."
- "[C]onsidering the role of third party certification in facilitating FDA determinations about pre-certification."

The New Paradigm for Software as a Medical Device

"FDA's **traditional approach** for the regulation of hardware-based medical devices is **not well-suited for the faster, iterative design and development**, and type of validation used for software device functions, including SaMD."

"An **agile regulatory paradigm is necessary** to accommodate the faster rate of development and potential for innovation in software-based products."



"In today's world of hardware-based medical devices, products are developed in months and years, but digital health products iterate more rapidly and frequently. These **iterations are often critical to manufacturers assuring that their products remain safe and effective**, and can protect the public from safety threats posed by their products."

The New Paradigm for Software as a Medical Device

1. Demonstrate a culture of quality and organizational excellence through an **Excellence Appraisal**.
2. Determine the SaMD's required review through **Review Determination**
3. Conduct a **Streamlined Review**
4. Verify a SaMD's continued safety, effectiveness and performance and the organization's commitment to culture of quality through post-market **Real-World Performance**.

- Product Quality – Demonstration of excellence in the development, testing, and maintenance necessary to deliver SaMD products at the highest level of quality.
- Patient Safety – Demonstration of excellence in providing a safe patient experience and emphasizing patient safety as a critical factor in all decision-making processes.
- Clinical Responsibility – Demonstration of excellence in responsibly conducting clinical evaluation and ensuring that patient-centric issues, including labeling and human factors, are appropriately addressed.
- Cybersecurity Responsibility – Demonstration of excellence in protecting cybersecurity and proactively addressing cybersecurity issues through active engagement with stakeholders and peers.
- Proactive Culture – Demonstration of excellence in a proactive approach to surveillance, assessment of user needs, and continuous learning.

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Critical = Life-threatening state of health, including incurable states; requires major therapeutic interventions
Serious = Moderate in progression, often curable; does not require major therapeutic interventions; intervention is normally not expected to be time critical
Non-serious = Slow with predictable progression of disease state; may not be curable; can be managed effectively; requires only minor therapeutic interventions; interventions are normally non-invasive

IMDRF Risk Categorization			Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD		
Type	**Subtype**	**Description**	**Initial Product**	**Major Changes**	**Minor Changes**
Type IV	*(9)*	Critical x Diagnose/Treat	Streamlined Review	Streamlined Review	No Review
Type III	*(8)*	Critical x Drive		L1 - Streamlined Review L2 - No Review	
Type III	*(7)*	Serious x Diagnose/Treat			
Type II	*(6)*	Serious x Drive	L1 - Streamlined Review L2 - No Review		
Type II	*(5)*	Non-serious x Diagnose/Treat		No Review	
Type II	*(4)*	Critical x Inform			
Type I	*(3)*	Non-serious x Drive	No Review		
Type I	*(2)*	Serious x Inform			
Type I	*(1)*	Non-serious x Inform			

The New Paradigm for Software as a Medical Device

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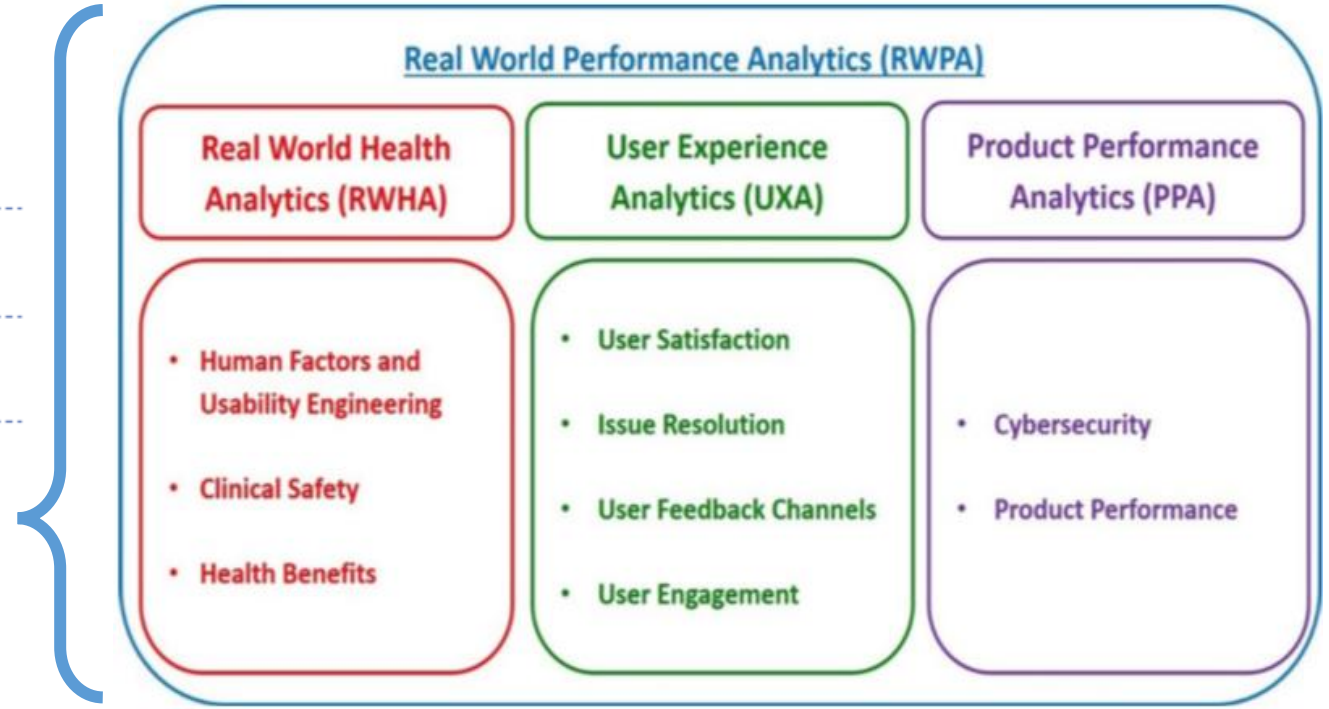
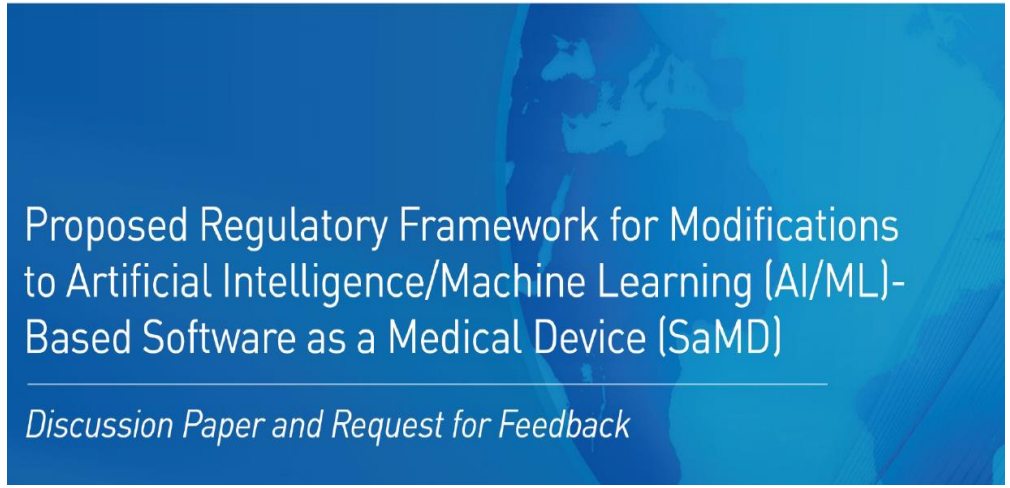
Real-World Health Analytics = analyses of real-world clinical outputs and outcomes related to the intended use of the SaMD product
User Experience Analytics = analyses of user experience outputs related to the real-world use of a SaMD product
Product Performance Analytics = analyses of outputs and outcomes demonstrating the real-world accuracy, reliability, and security of a SaMD product



The New Paradigm for Software as a Medical Device



Total Product Lifecycle Approach

- Establish clear expectations on **quality systems** and good ML practices (GMLP)*
- Conduct **premarket review** and establish clear expectations to continually manage patient risks
- Expect manufacturers to **monitor** the device **and incorporate a risk management** approach in development, validation, and execution of the changes
- Enable **increased transparency** to users and FDA using postmarket **real-world performance reporting**

Good Machine Learning Practice for Medical Device Development: Guiding Principles

October 2021

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent of Test Sets
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-training Risks are Managed

The New Paradigm for Software as a Medical Device

CDRH Proposed Guidances for Fiscal Year 2022

A-List: Prioritized Guidance Documents that CDRH Intends to Publish in FY2022

Final Guidance Topics

- Clinical Decision Support Software

Draft Guidance Topics

- Computer Software Assurance for Production and Quality System Software
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Content of Premarket Submissions for Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD)

B-List: Guidance Documents that CDRH Intends to Publish, as Guidance Development Resources Permit in FY2022

Final Guidance Topics

- Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations

Draft Guidance Topics

- Content of Human Factors Information in Medical Device Marketing Submissions
- Marketing Submission Recommendations for A Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions
- Risk Categorization for Software as a Medical Device: FDA Interpretation, Policy, and Considerations

Which Software IS an FDA-Regulated Medical Device?

A. A software function that **stores, processes, and analyzes claims data** to help ensure timely and compliant billing

B. A software function that **provides access to medical literature** with generic text search capabilities

C. A software function that simulates various cardiac arrest scenarios to **train a HCP in advanced CPR skills**

D. A software function that solely **monitors and records daily energy expenditure and cardiovascular workout activities** to allow awareness of one's exercise activities to **improve or maintain good cardiovascular health**

E. A software function that **analyzes a previously stored electrocardiogram** for a particular patient and **provides a notification** as to the potential for atrial defibrillation

Which Software IS an FDA-Regulated Medical Device?

A. A software function that **helps asthmatics record (i.e., collect and log) inhaler usage, asthma episodes** experienced, location of user at the time of an attack, or environmental triggers of asthma attacks

B. Software functions that use an attachment to a mobile platform to **measure blood oxygen saturation for diagnosis of specific disease** or condition

C. Mobile apps that use GPS location information to **alert asthmatics of environmental conditions** that may cause asthma symptoms or alert an addiction patient (substance abusers) when near a pre-identified, high-risk location

D. Software functions that **coach patients** with conditions (e.g., cardiovascular disease, hypertension, diabetes, or obesity) and promote strategies for **maintaining a healthy weight**, getting optimal nutrition, exercising and staying fit, managing salt intake, or **adhering to pre-determined medication dosing schedules** by simple prompting

Which Software IS NOT an FDA-Regulated Medical Device?

A. A software tool that **analyzes a patient's stored clinical information** based on specific clinical parameters **to make recommendations to a HCP** and opportunities for complementary tests, and the **basis for the recommendation is provided** so that the HCP does not rely primarily on the recommendation

B. Software that **manipulates or analyzes images and other data obtained from a radiological device** (e.g., CT, bone density, and distance) **to create 3D models** of the region intended to be **used in planning** orthopedic/dental surgical treatments with a device

C. Software intended for patients that **provides a questionnaire to assess a patient's level of stress and anxiety** (prior to any diagnosis of general anxiety disorder) **and recommends treatment options** based on the output of the assessment

D. Machine-learning algorithm, for which the logic and inputs are not explained, that **categorizes likely symptoms of seasonal influenza** for each flu season based on location and current electronic health records of patients diagnosed or suspected to have influenza **to assist HCPs in differentiating between common flu symptoms and other illnesses** (e.g., common cold) in a particular season

BROOKE CONSULTING, LLC

Digital Health Legal & Regulatory Advisors

Jason@Brooke-Consulting.com

shelby.l.buettner@medtronic.com