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FDA Digital Health Updates: What has Changed in 2022 and What should you be expecting in 2023

Allison Komiyama and Kevin Go

December 1, 2022

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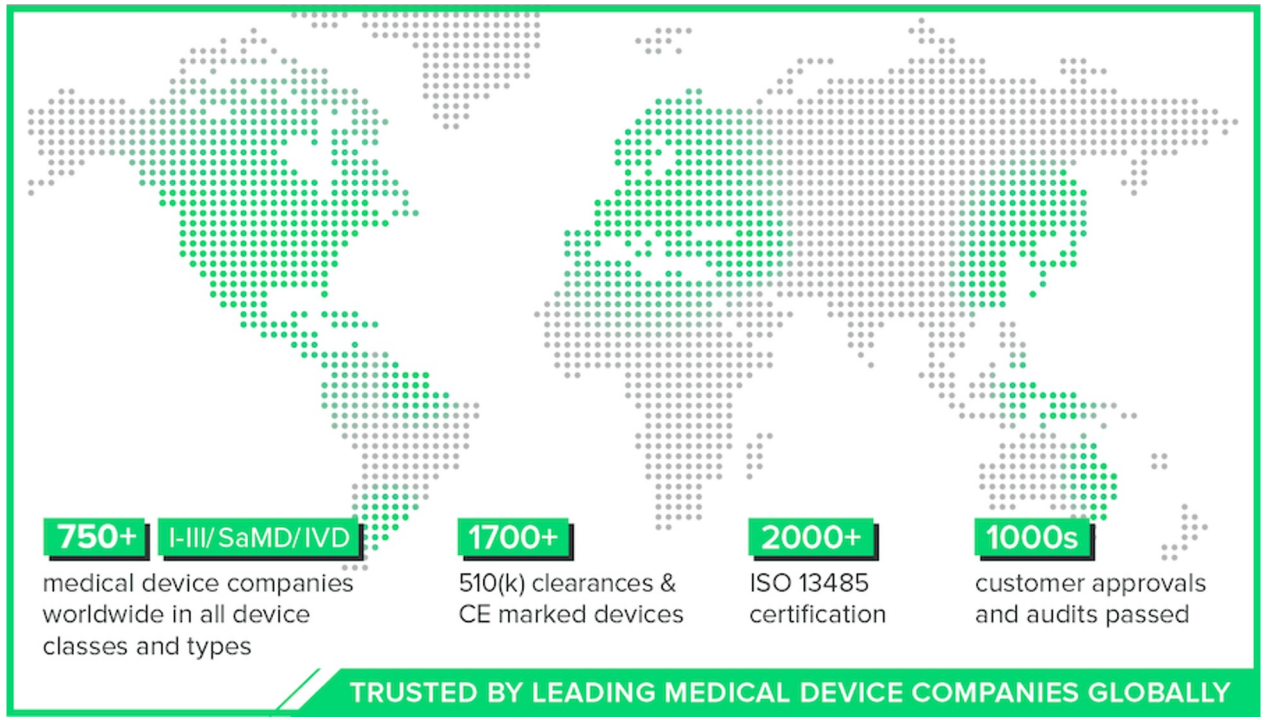

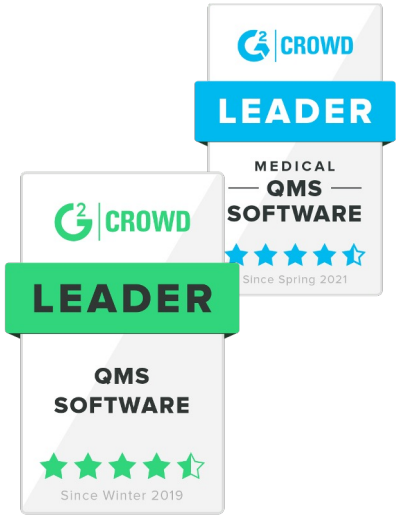

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RQM+ is the leading MedTech service provider with the world's largest global team of regulatory and quality experts. We provide comprehensive regulatory, quality, clinical, and laboratory services, supporting market access throughout the entire product lifecycle for medical devices and diagnostics.

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RQM+ Services

Regulatory Affairs

- Worldwide regulatory strategies
- FDA 510(k), PMA, De Novo, IDE, EUA, Breakthrough, and Pre-Subs
- CE marking strategy, technical documentation and sustaining support
- EU MDR/IVDR – complete transition solution
- RA leadership/support to new product development teams
- Strategic direction on labeling, regulations and standards
- Acquisition due diligence & integration

Design Quality Engineering

- Design control assurance to new product development teams
- Safety risk management, including implementation of EU MDR/IVDR
- DHF and technical documentation gap analysis and remediation – proactive or reactive

Clinical Regulatory Affairs

- EU MDR CERs (includes CEP, literature searches, S&P and SotA)
- IVDR PERs (includes PEP, literature searches, SotA, CP, SV and AP)
- Clinical-regulatory strategy
- Clinical/performance evidence matrix development
- Clinical regulatory affairs training
- Ongoing maintenance and updates of CERs/PERs, and other MDR/IVDR documentation.
- MDR SSCP and IVDR SSP

Post-Market Surveillance

- Worldwide PMS including EU MDR/IVDR
- Strategy and Integration of PMS, CER/PER, and risk management
- PMS procedures, plans and reports
- Periodic Safety Update Reports (PSUR)
- PMCF & PMPF plans, reports and user surveys (PMCF)
- Complete managed outsourcing service

Quality Systems

- Quality system development: ISO 13485, QSR, EU MDR, MDSAP
- Quality system improvements and remediation
- Internal audits
- Supplier quality and audits
- Economic operator audits
- FDA inspection readiness and support
- EU MDR/IVDR mock NB audits
- Acquisition integration

Regulatory Compliance

- Complete strategic remediation solution – leadership, project management and scalable team for execution
- Regulatory agency audit findings – strategy and response
- Corrective action and remediation planning and leadership
- Recall strategy and execution
- 483s, warning letters, consent decrees and NB non-conformity reports

Manufacturing Quality Engineering

- Quality assurance of manufactured product
- Process improvements and validation/qualification
- Computer systems validation
- Packaging validation
- Sterilization validation
- Manufacturing site transfer
- Strategy and implementation of EU MDR/IVDR requirements

Laboratory Services

- Extractables and leachables (E&L) testing
- Product deformulation
- Investigative polymer analysis & quality control
- Biological consulting
    - *Product development strategy*
    - *Biological evaluations (in-vitro and in-vivo testing)*
    - *Risk assessments*

Presenters

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Agenda

01 Background and Terminology

02 New Guidance Documents and Application to Regulatory Strategy/Submissions

03 New Digital Health Tools (e.g., eSTAR, CCP)

04 Other Regulatory Developments for Digital Health Products

05 What's Next for Digital Health Products?

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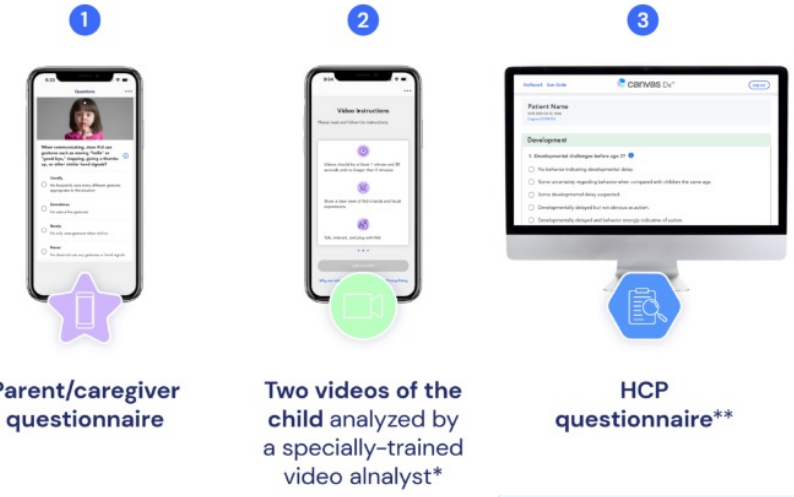
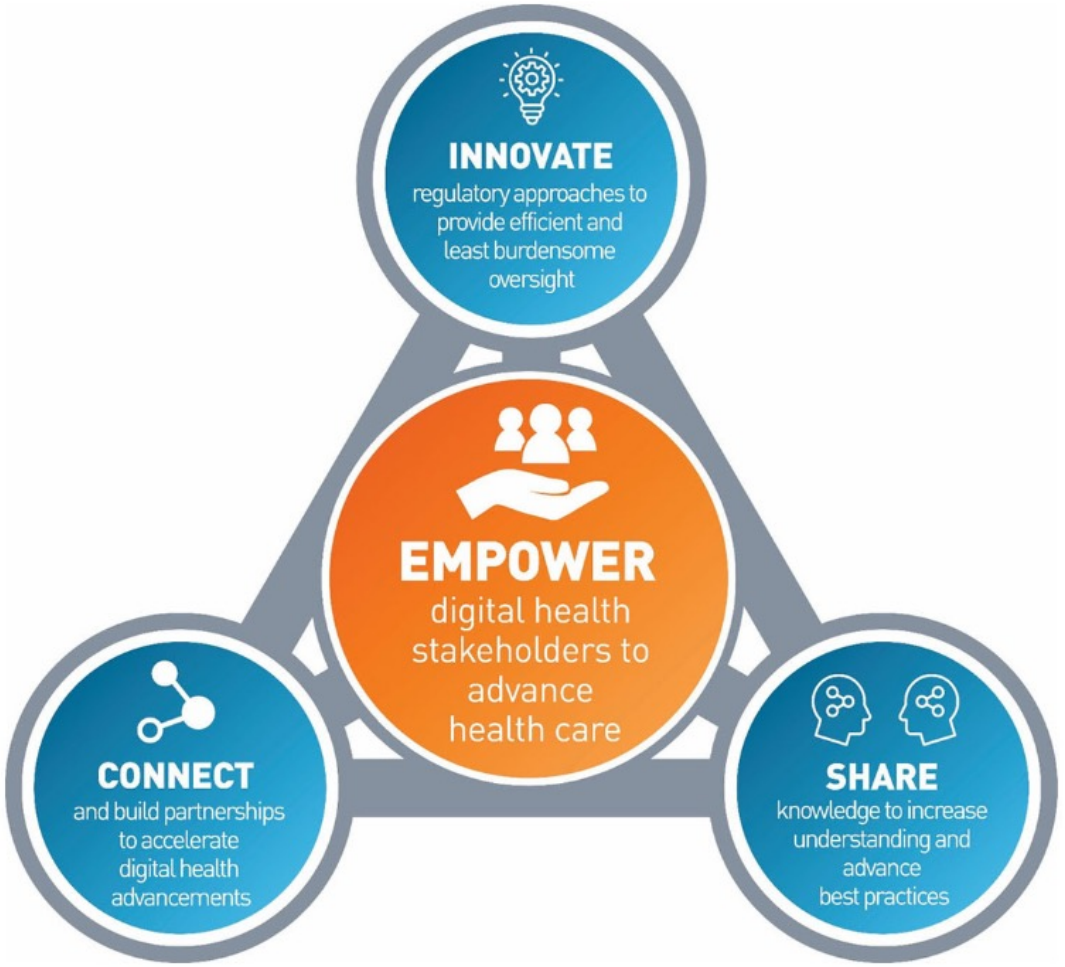
Background



https://ebay.com https://www.edwards.com https://rarehistoricalphotos.com https://cognoa.com/

Background

- FDA's Digital Health Center of Excellence
  - Founded 2020
- Key goals of FDA's Digital Health Innovation Action:
  - New guidance
  - Reimagining digital health product oversight
  - Growing expertise at FDA
- Result:
  - Lots of Changes in 2022 and many more coming in 2023!



Source: https://www.fda.gov/medical-devices/digital-health-center-excellence/about-digital-health-center-excellence

What is Digital Health?

- The broad scope of digital health includes categories such as:
  - Mobile Health (mHealth)
  - Health Information Technology (IT)
  - Wearable Devices
  - Telehealth/Telemedicine
  - Personalized Medicine
- Technology varies from general wellness applications to digital therapeutics (DTx) and digital diagnostic (DDx) devices
- Can be standalone medical product (SaMD), in a medical product (SiMD), as a companion diagnostic (CDx), as an adjunct to other medical products (CDS, RPM or MMA), or used to develop/study other medical products (MDDT)

Device and Device Software Functions Definition

Device Definition per Section 201(h) of FD&C	Device Software Function per FDA Guidance "Policy for Device Software Functions and Mobile Medical Applications" (September 28, 2022)
*An **instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent,** or other similar or related article, including any component, part, or accessory, which is:* *a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,* *b) intended for use in the **diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease**, in man or other animals, or* *c) intended **to affect the structure or any function of the body** of man or other animals, and **which does not achieve its primary intended purposes through chemical action** within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.*	*1. Software functions that are an **extension of one or more medical devices** by connecting to such device(s) **for purposes of controlling the device(s) or analyzing medical device data**.* *2. Software functions (typically, mobile apps) that **transform the mobile platform into a regulated medical device** by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Software functions that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device **are required to comply with the device classification associated with the transformed platform.*** *3. Software functions that become a regulated medical device by **performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.** These types of functions are similar to or perform the same function as those types of software devices that have been previously cleared or approved.*

Software as a Medical Device (SaMD) Definition

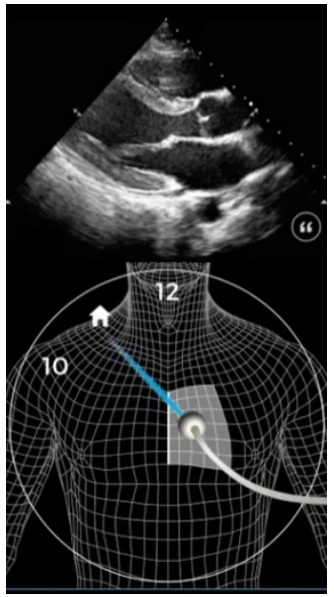
Source	Definition
FDA	*Software intended for one or more medical uses that may run on different operating systems or in virtual environments. Software run on a hardware medical device is a SaMD when not part of the intended use of the hardware medical device. Software is not SaMD if it drives or controls the hardware medical device.* *This can include standalone software that is intended to run on general purpose computers or mobile platforms (that is, smartphone, tablet).*
IEC 62304 – Medical Device Software – Software Life Cycle Processes	*Medical device software system that has been developed for the purpose of being incorporated into the medical device being developed or that is intended for use as a medical device. Note: This includes a medical device software product, which then is a medical device in its own right.*
International Medical Device Regulators Forum (IMDRF)	*Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.*

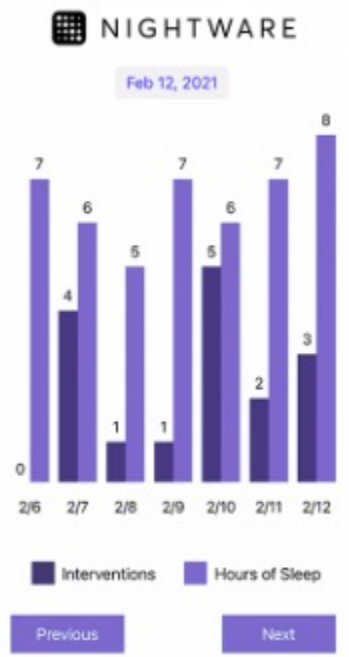
Other Important Definitions

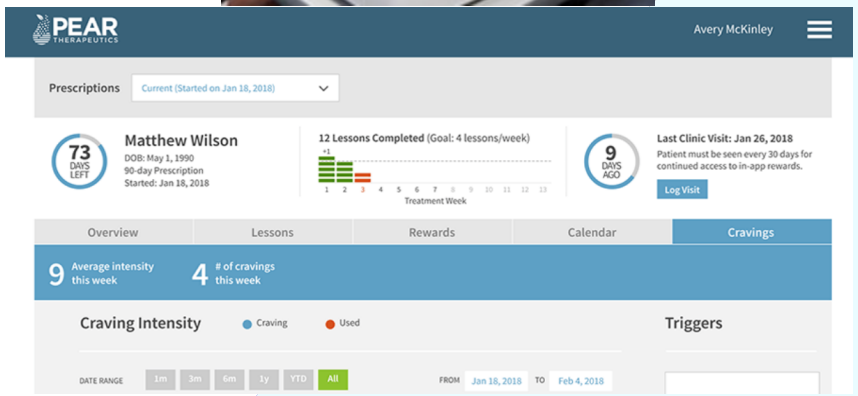
Source	Definition
Artificial Intelligence (AI)	*A device or product that can **imitate intelligent behavior or mimics human learning and reasoning**. Artificial intelligence includes machine learning (ML), neural networks, and natural language processing. Some terms used to describe artificial intelligence include: computer-aided detection/diagnosis, statistical learning, deep learning, or smart algorithms.* Can have “locked” or adaptive algorithms.
Cybersecurity	*A device or product that can **prevent unauthorized access, modification, misuse, or denial of use, or the unauthorized use of information** which is stored, accessed, or transferred from a medical device to an external recipient.*
Interoperability	*A device or product that can **exchange and use information through an electronic interface** with another medical/non-medical product, system, or device.*

Examples of Digital Health Devices

- Radiological AI/ML SaMD
  - Image Acquisition and/or Optimization Guided by AI Caption Guidance (DEN190040)
- Mobile Medical Apps (MMA)
  - ECG App for Apple Watch (DEN180044)
  - Irregular Rhythm Notification Feature for Apple Watch (DEN180042)
- Digital Therapeutics (DTx)
  - Reduce sleep disturbance in patients with PSTD (DEN200033)
  - CBT for Psychiatric Disorders (DEN160018)
- Digital Diagnostics (DDx)
  - Diagnostic screening to identify retinal diseases or conditions (DEN180001)

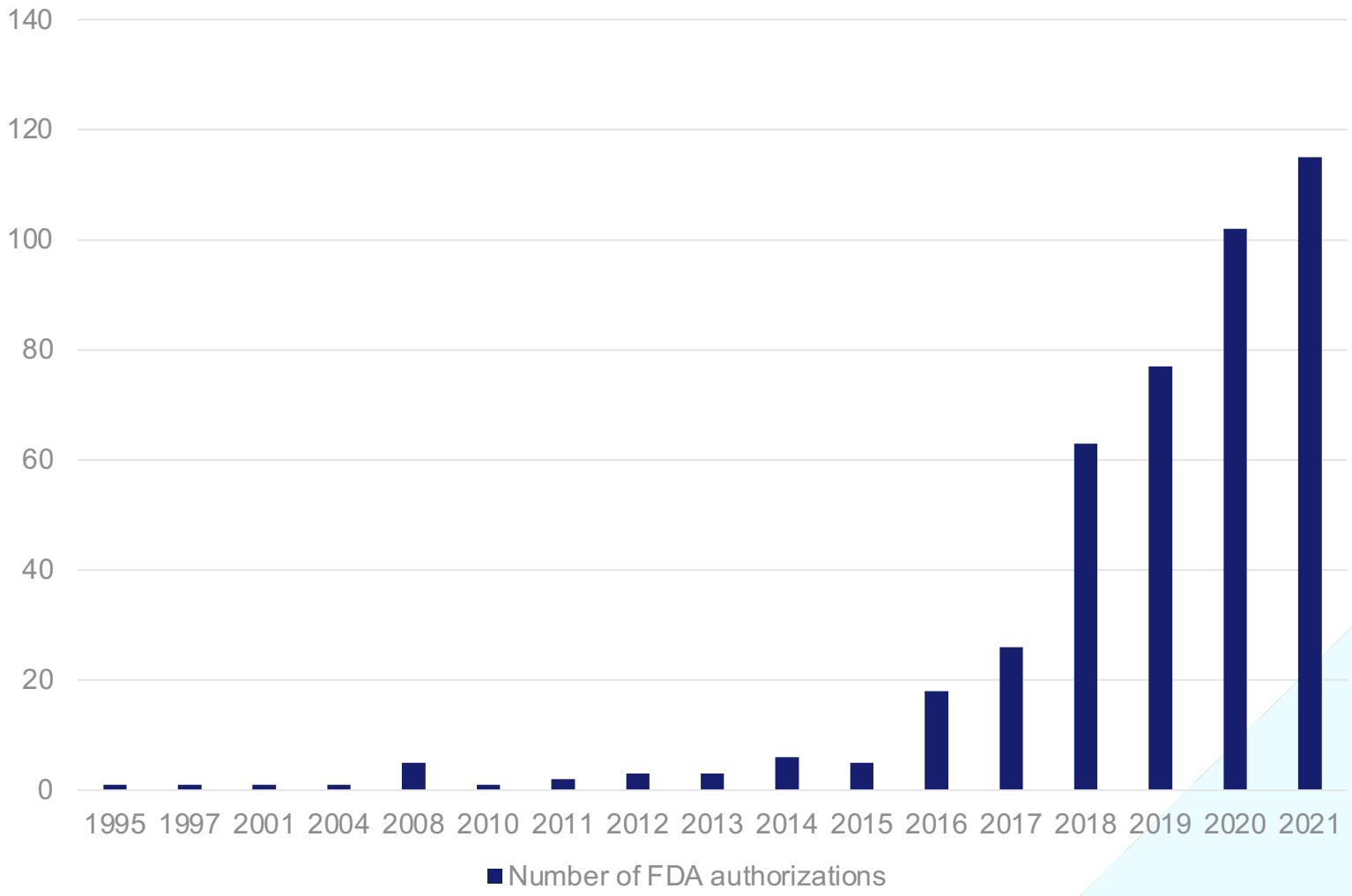






https://captionhealth.com/technology https://support.apple.com https://nightware.com https://www.digitaldiagnostics.com/ https://peartherapeutics.com/

Increase in AI-enabled Med Devices



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FDA Removes Certain Software Functions from Device Definition

- The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, is designed to help accelerate medical product development and innovations.
- The Cures Act **amended the definition of "device"** in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to **exclude** certain software functions:
  - Software Function Intended for Administrative Support of a Health Care Facility
  - Software Function Intended for Maintaining or Encouraging a Healthy Lifestyle (General Wellness Devices)
  - Software Function Intended to Serve as Electronic Patient Records
  - Software Function Intended for Transferring, Storing, Converting Formats, Displaying Data and Results (Medical Device Data System (MDDS))
- FDA also issued other guidance on Clinical Decision Support (CDS) Software and Multiple Function Device Products

New Digital Health Guidance Documents - 2022

- Final
  - Policy for Device Software Functions and Mobile Medical Applications
  - Clinical Decision Support Software Guidance
  - Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
  - Computer-Assisted Detection (CAD) Devices
    - Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions
    - Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions
- Draft
  - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Policy for Device Software Functions and Mobile Medical Applications

- New Guidance issued September 28, 2022
- Scope:
  - **Mobile Platforms** – computing platforms such as smart phones, tablet computers, or other portable computers
  - **Mobile Medical Application** (MMA) – a mobile app that incorporates device software functionality that meets the definition of a device and either is intended:
    - To be used as an accessory to a regulated medical device; or
    - To transform a mobile platform into a regulated medical device.
  - **Other Software Functions** – that do not meet the definition of a device, software functions which may meet the definition but for which FDA intends to exercise enforcement discretion, and software functions which do meet the definition of a device

Policy for Device Software Functions

Software Classifications	Definitions
Device Software Functions, which are the **focus of FDA's regulatory oversight**	Software functions that are considered medical devices (i.e., device software functions), and on which FDA will focus its regulatory oversight.
Software Functions for which FDA intends to **exercise enforcement discretion**	Software functions that may meet the definition of medical device but for which FDA intends to exercise enforcement discretion due to the lower risk. (e.g., General Wellness Devices)
Software Functions that are **NOT Medical Devices**	Software functions that could be used in a health care environment, in clinical care, or patient management, but are not considered medical devices. Therefore, FDA does not regulate them. (e.g. MDDS)

Software Functions that are the focus of FDA oversight

1. Software functions that are an **extension of one or more medical devices** by connecting to such device(s) **for purposes of controlling the device(s) or analyzing medical device data**.
2. Software functions (typically, mobile apps) that **transform the mobile platform into a regulated medical device** by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Software functions that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device **are required to comply with the device classification associated with the transformed platform.**
3. Software functions that become a regulated medical device by **performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.** These types of functions are similar to or perform the same function as those types of software devices that have been previously cleared or approved.

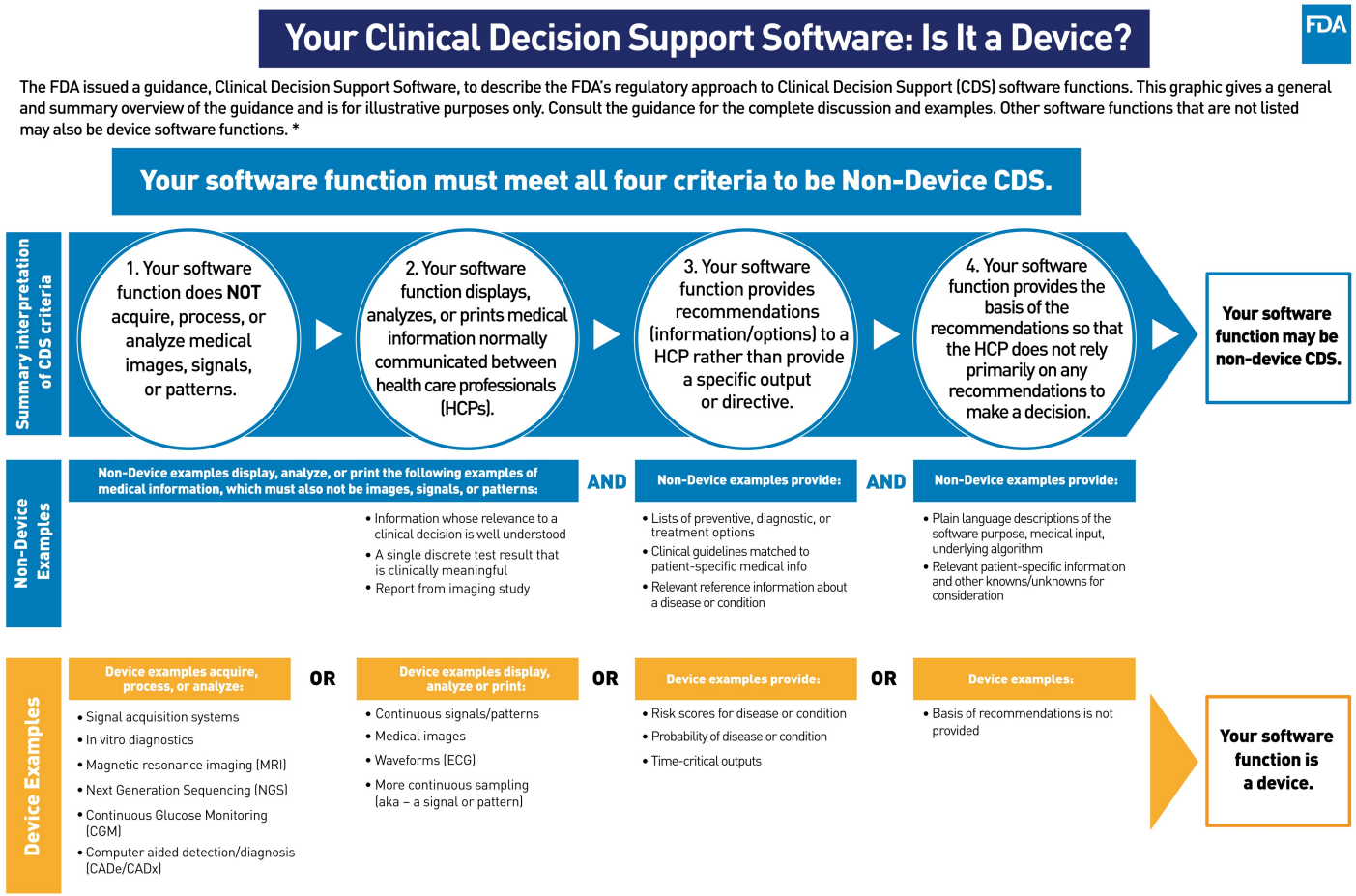
Clinical Decision Support Software Guidance

- Certain CDS software functions are **excluded from the definition of device** by section 520(o)(1)(E) of the FD&C Act if the software functions **meet all of the following four criteria**:
  1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system (section 520(o)(1)(E) of the FD&C Act);
  2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);
  3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition (section 520(o)(1)(E)(ii) of the FD&C Act); and
  4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (section 520(o)(1)(E)(iii) of the FD&C Act).

Clinical Decision Support Software Guidance

- New Guidance issued September 28, 2022
- There have been Significant changes from the draft guidance. A few key changes:
  - Only Device CDS (regulatory oversight) vs Non-Device CDS (no regulatory oversight)
  - FDA provides further clarification on their interpretation of the four CDS criteria
    - Signal vs Pattern (single vs continuous)
    - Level of Software Automation and Time-Critical Nature of the HCP's decision making can increase risk of the device and exceed the limitations of Criteria 3 ("supporting or providing recommendations")
    - Basis of recommendations is not provided can exceed limitation

Your CDS Software: Is it a Device?



*Disclaimer: This graphic gives a general overview of Section IV of the guidance ("Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act"). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.

https://www.fda.gov/medical-devices/software-medical-device-samd/your-clinical-decision-support-software-it-medical-device

MDDS Guidance Document

- New Guidance issued September 28, 2022
- **Non-Device MDDS**: Software functions that are **solely intended to transfer, store, convert formats, or display medical device data and results**
  - Software functions that meet the definition of Non-Device MDDS are **not** considered devices are not subject to FDA device requirements
  - If software functions analyze or interpret, then it does **not** meet the non-Device MDDS definition

MDDS Guidance Document

- **Device MDDS**: Hardware functions that are solely intended to transfer, store, convert formats, or display medical device data and results and does not modify the data, control the functions or parameters of any connected medical device.
  - FDA does **not intend to enforce requirements** under the FD&C Act for hardware functions are considered Device MDDS
  - May include the following regulations:
    - a) MDDS subject to 21 CFR 880.6310,
    - b) Medical image storage devices subject to 21 CFR 892.2010 and
    - c) Medical image communications devices subject to 21 CFR 892.2020.
  - Software functions that serve the same functions that are utilized on hardware not intended by the hardware manufacturer for a device function also does not meet the definition of a device.

Key Takeaways for Determining if your Product is a Medical Device

- Identify the intended use
  - Is your product intended to *"diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease"?*
- Determine the functions of the device
  - The term "function" means a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product.
  - Products may have one or multiple functions.
  - Some multiple function device products may include both Device Software Functions and Non-Device software functions (CDS or otherwise).
- Look up other FDA-cleared predicates or commercially available products

Digital Health Policy Navigator

For comprehensive policy feedback, complete the steps for EACH of your product's software functions:

- Step 1: Is the software function intended for a medical purpose?
- Step 2: Is the software function intended for administrative support of a health care facility?
- Step 3: Is the software function intended for maintaining or encouraging a healthy lifestyle?
- Step 4: Is the software function intended to serve as electronic patient records?
- Step 5: Is the software function intended for transferring, storing, converting formats, or displaying data and results?
- Step 6: Is the software function intended to provide clinical decision support?
- Step 7: Does the Device Software Functions and Mobile Medical Applications Guidance apply?

Icon	Outcome	Meaning
	LIKELY NOT A DEVICE	Device requirements do not apply if the software function is not a device.
	LIKELY FDA INTENDS TO EXERCISE ENFORCEMENT DISCRETION	Some software functions may meet the definition of a device, but because they pose a lower risk, the software function may fall within FDA's enforcement discretion policy (meaning that the FDA does not intend to enforce applicable requirements under the FD&C Act at this time).
	LIKELY THE FOCUS OF FDA'S REGULATORY OVERSIGHT	The software function is a device and its functionality could pose a risk to a patient's safety if the device were to not function as intended. Devices may be subject to requirements such as premarket authorization (e.g., premarket notification (section 510(k) of the FD&C Act), De Novo (section 513(f)(3) of the FD&C Act), premarket approval (section 515 of the FD&C Act)), adverse event reporting (section 519 of the FD&C Act), among others.
	Your product may be a device. Go to Step #.	More information is needed to identify the relevant policies. Go to the next Step.

Computer-Assisted Detection Devices Guidances

- Two new Guidance Documents have been released on September 28, 2022
  - Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions
  - Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions
- Refer to these Guidance Documents for more **details and general information about types and levels of detail FDA would like to see about AI/ML algorithm** even for non- CADe devices.
- These documents also include additional recommendations and requirements, such as:
  - **Locking the device** so that no further modifications are made during or after the standalone/clinical evaluations
  - Importance of the **train/test datasets are completely independent** of each other to avoid data leakage

Digital Guidance Documents

List of FDA Guidance Documents with Digital Health Content

Search: Show 100 entries

Issue Date	Guidance	Guidance Status
09/28/2022	Clinical Decision Support Software	Final
09/28/2022	Policy for Device Software Functions and Mobile Medical Applications	Final
09/28/2022	Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices	Final
04/08/2022	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	Draft
12/23/2021	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations	Draft
11/04/2021	Content of Premarket Submissions for Device Software Functions	Draft
11/04/2020	Multiple Function Device Products: Policy and Considerations	Final
09/27/2019	Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act	Final
09/27/2019	General Wellness: Policy for Low Risk Devices	Final
09/27/2019	Off-The-Shelf Software Use in Medical Devices	Final
12/20/2017	Medical Device Accessories - Describing Accessories and Classification Pathways	Final
12/08/2017	Software as a Medical Device (SAMD): Clinical Evaluation	Final
10/25/2017	Deciding When to Submit a 510(k) for a Software Change to an Existing Device	Final
09/06/2017	Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices	Final
12/28/2016	Postmarket Management of Cybersecurity in Medical Devices	Final
02/03/2016	Applying Human Factors and Usability Engineering to Medical Devices	Final
09/02/2014	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices	Final
08/14/2013	Radio Frequency Wireless Technology in Medical Devices	Final
07/03/2012	Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions	Final
07/03/2012	Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions	Final

https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content

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Electronic Submission Template and Resource (eSTAR)

- eSTAR is an interactive/dynamic PDF form that guides applicants through the process of preparing a comprehensive medical device submission. This template contains:
  - Automation (e.g., form construction, autofill)
  - Content & structure complimentary to CDRH internal review templates
  - Integration of multiple resources (e.g., guidances, databases)
  - Guided construction for each submission section
  - Automatic verification
- Final Guidance released September 22, 2022, making eSTAR mandatory for all 510(k) Submissions on October 1, 2023
- Includes helpful sections for software devices including:
  - Listing all software document requirements
  - Cybersecurity requirements
  - Interoperability requirements

eSTAR

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	(•) New Application/Submission ( ) Additional Information

1

2

1) Selecting Application Purpose unlocks sections to be completed

2) Application Type further refines the application

eSTAR

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

Komiyama Implant	ACK123	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	Yes
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	No
• Please check the attributes that are applicable to your device.	☐ Cloud C… ☐ Networ… ☒ Wireles… ☐ USB/se… ☐ Softwar… ☐ None of…
Is the device or a component packaged as sterile?	
The device/system uses or is... (choose all that apply)	☒ a single use device ☐ a single use device… ☐ a reusable single p… ☐ a reusable multi-pa…
The environment of use of the device/system includes... (choose all that apply)	☐ Pro… ☐ Hor… ☐ Mag… ☐ Tra… ☐ Oth…
Is the device a combination product?	
Is the device electrical (battery or wall powered)?	
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

JavaScript Window

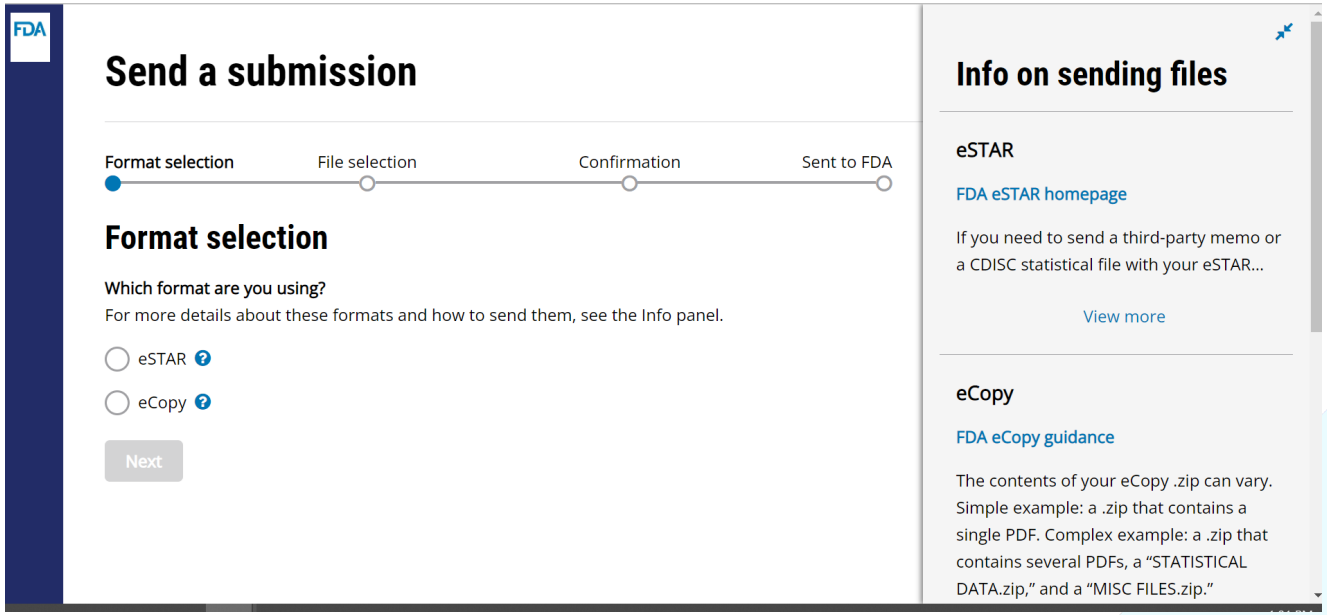
Ensure the single use device/component is labeled "Do Not Reuse," "Single Use," or "Single Use Only," and optionally with the symbol depicted below, which appears as the number "2" within a black circle and slash. (AAMI/ANSI ES 60601-1 Cl. 7.2.1)

OK

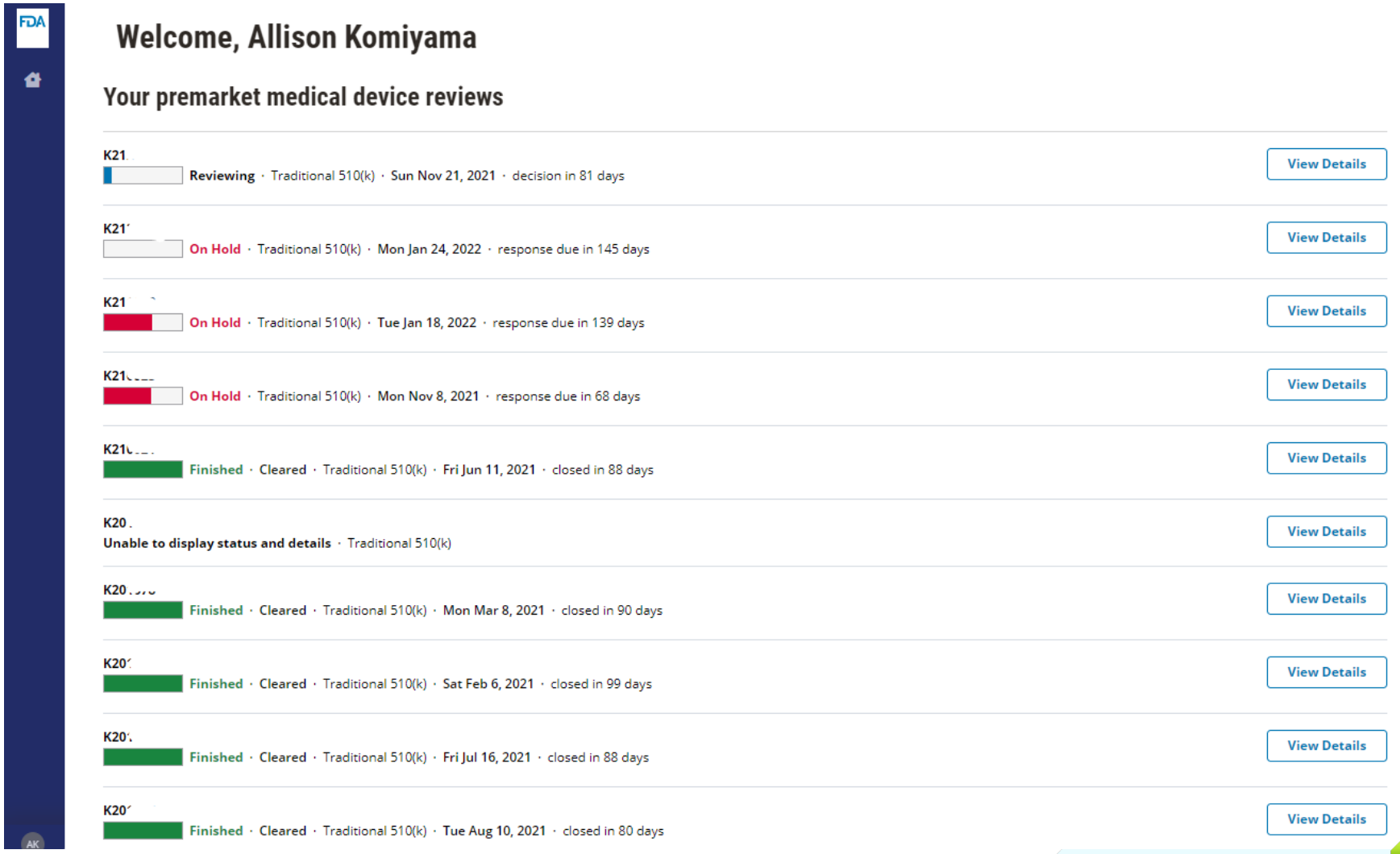
Warning: JavaScript Window

Customer Collaboration Portal ("CCP")

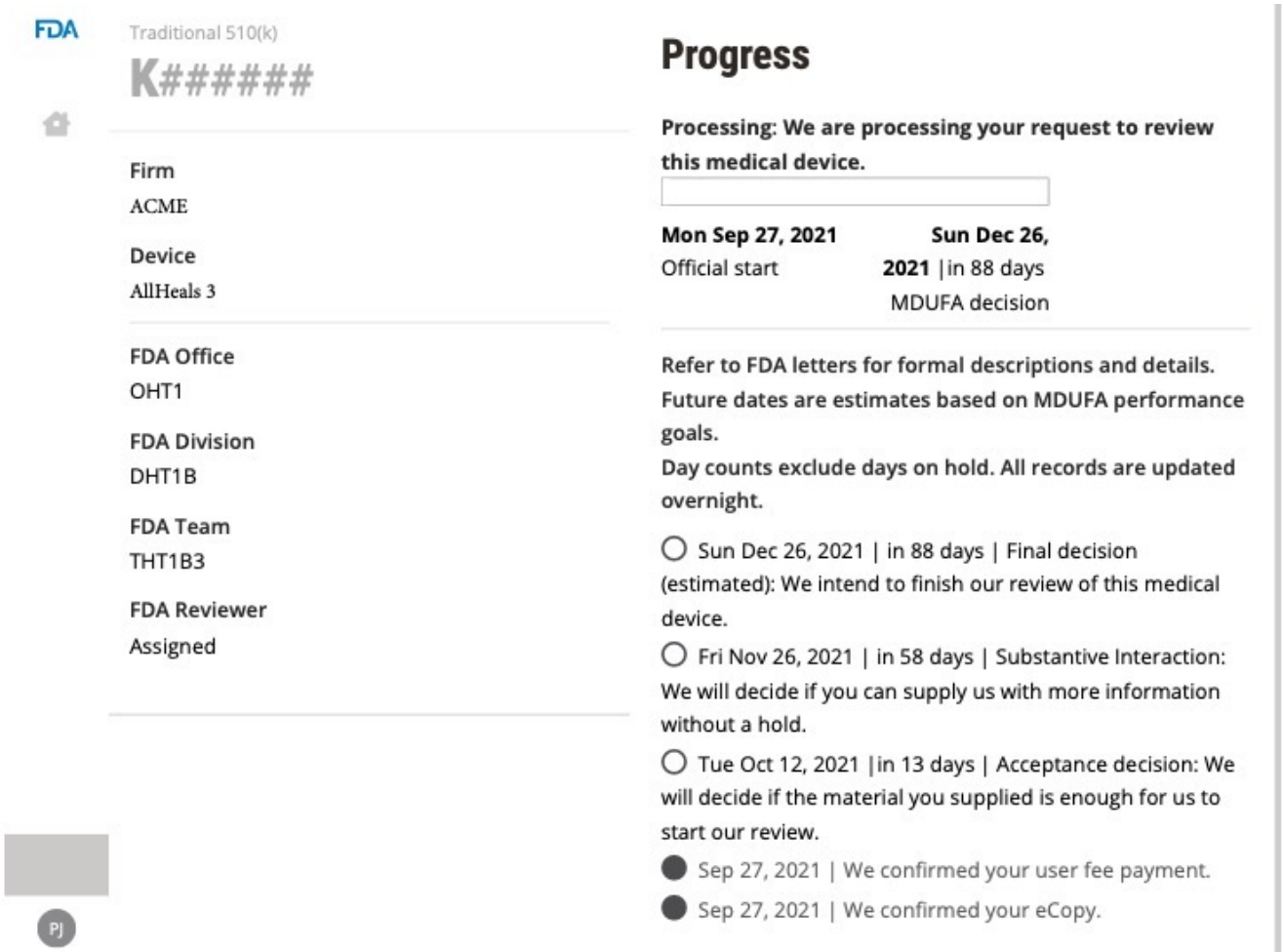
- Secure, web-based tracker which allows user to submit submission online as either eCopy or eSTAR
- Displays the Center for Devices and Radiological Health's (CDRH) progress in reviewing Traditional, Abbreviated, and Special 510(k) submissions.
- Was previously in trial but was opened this year to everyone.



Customer Collaboration Portal (“CCP”)



Customer Collaboration Portal (“CCP”)



Agenda

01 Background and Terminology

02 New Guidance Documents and Application to Regulatory Strategy/Submissions

03 New Digital Health Tools (e.g., eSTAR, CCP)

04 Other Regulatory Developments for Digital Health Products

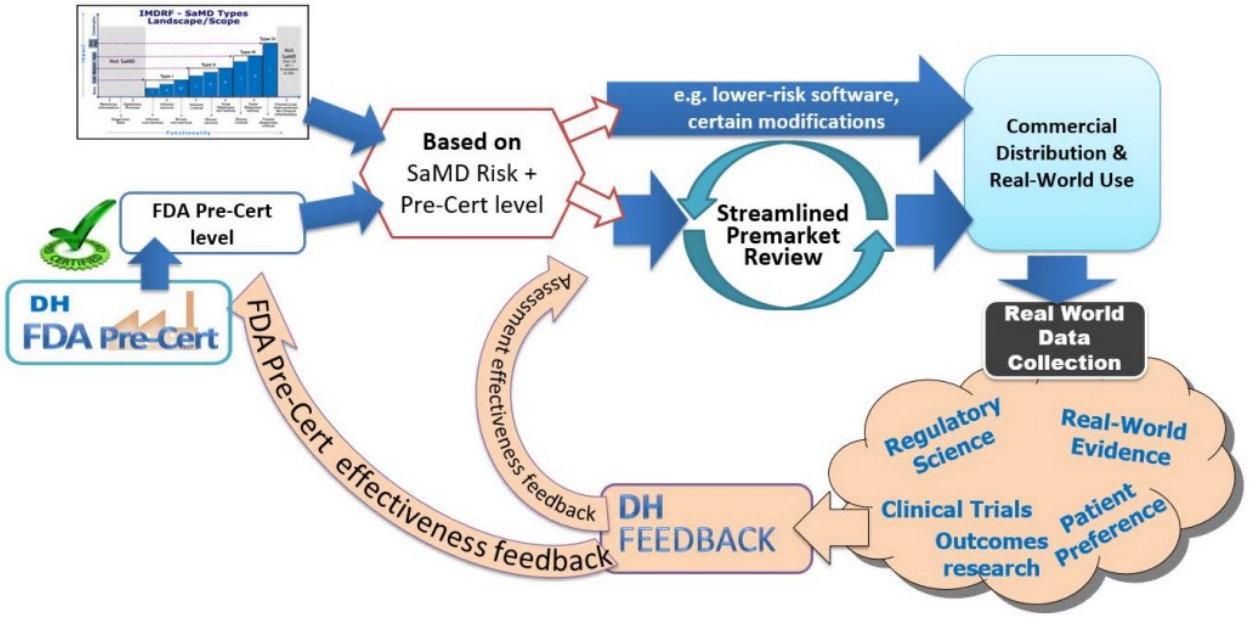
05 What's Next for Digital Health Products?

AI/ML Considerations on Marketing Pathway

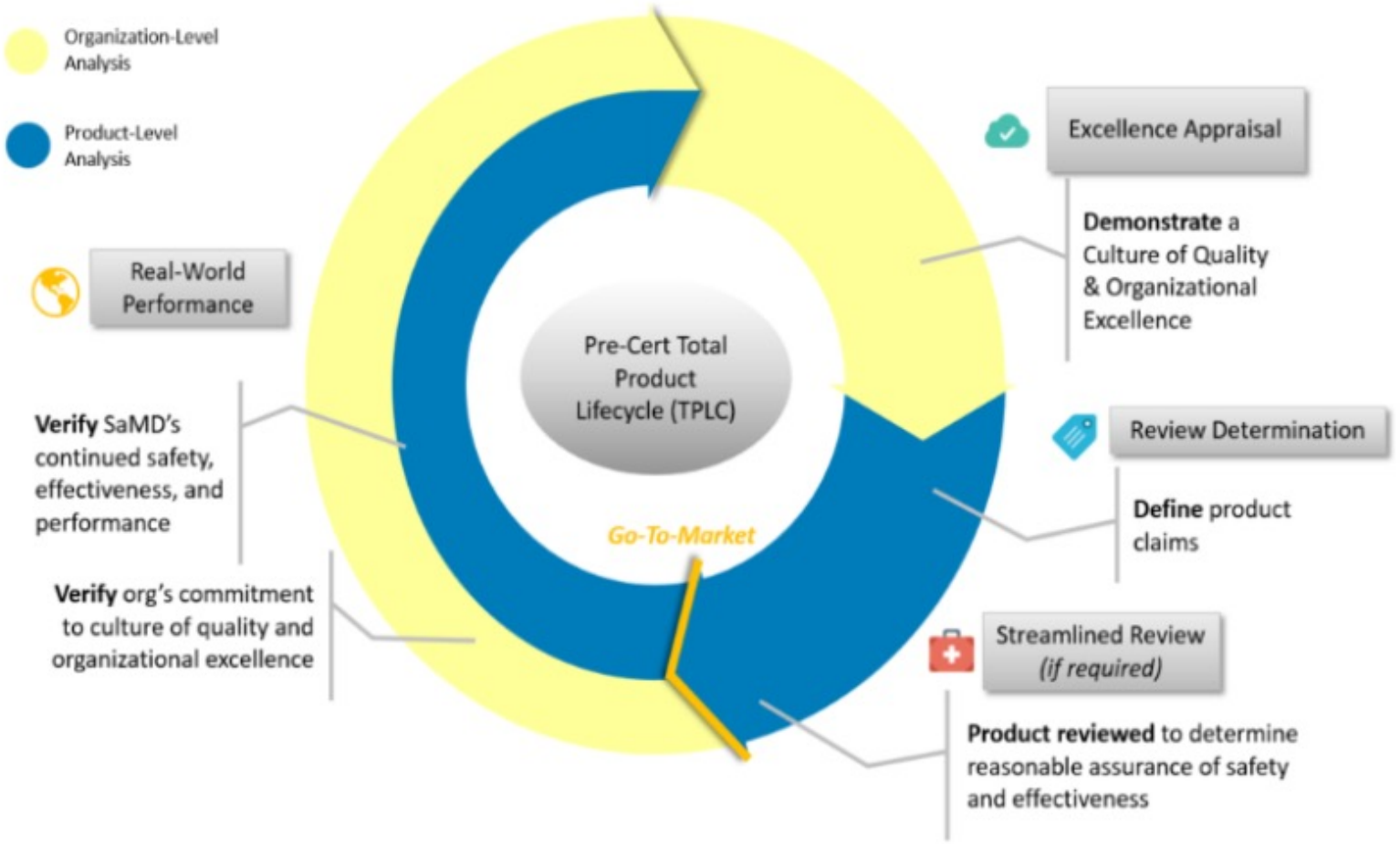
- FDA has only allowed “locked” algorithms onto the market. No adaptive algorithms have yet to be cleared
- Adding AI/ML to a device can introduce new risks and possibly change the risk classification
  - E.g., Adding AI to a Class 1 (exempt) device may exceed the limitations of exemption and require a 510(k)
- Adding a Predetermined Change Control Plan (PCCP) may raise **different** questions of safety and effectiveness if the predicate does not have it or it is not part of the Special Controls
  - If you are considering submitting a PCCP, FDA highly recommends that you submit a dedicated Pre-Submission

Digital Health Software Precertification Pilot Program

- The Pre-Cert pilot was completed in September 2022
- "*The faster cycles of innovation and the speed of change for medical device software would benefit from a new regulatory approach…New legislative authority establishing such an approach could be supplemental to, and not replace, the established regulatory pathways.*"



Digital Health Software Precertification Program



Digital Health Software Precertification Program – Excellence Principles

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.

- Apple
- Fitbit
- Johnson & Johnson
- Pear Therapeutics
- Phosphorus
- Roche
- Samsung
- Tidepool
- Verily

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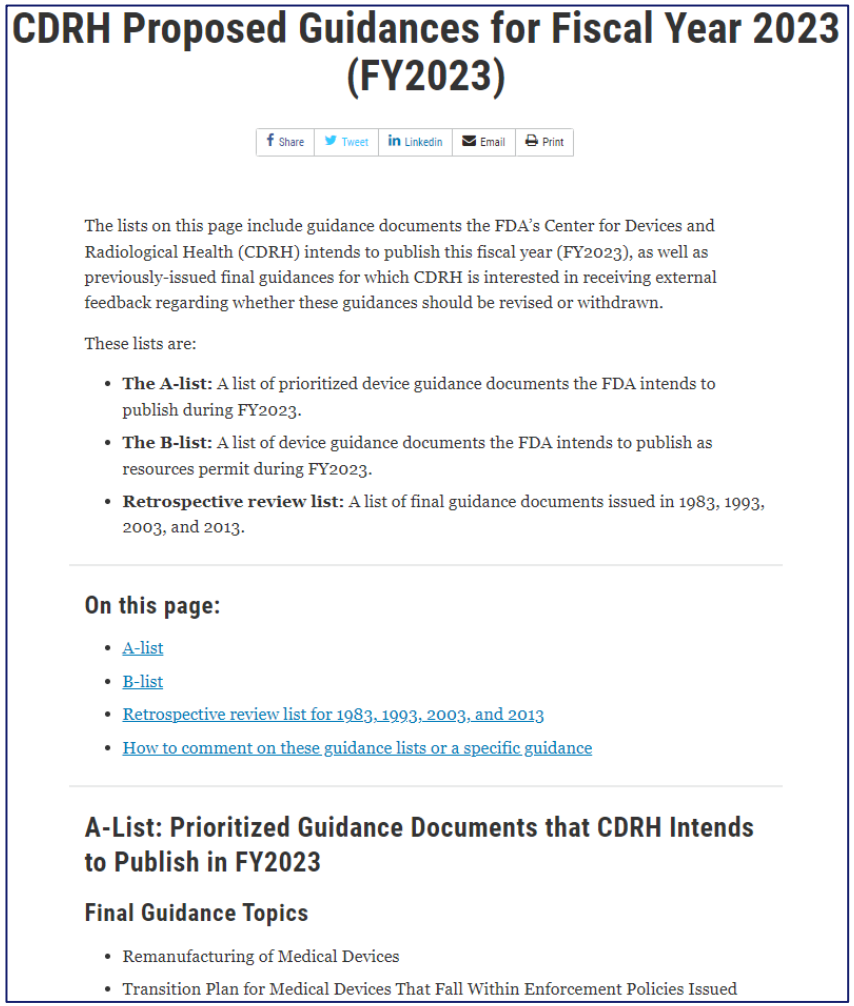
Future Guidance Documents



CDRH Proposed Guidances for Fiscal Year 2023 (FY2023)

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The lists on this page include guidance documents the FDA's Center for Devices and Radiological Health (CDRH) intends to publish this fiscal year (FY2023), as well as previously-issued final guidances for which CDRH is interested in receiving external feedback regarding whether these guidances should be revised or withdrawn.

These lists are:

- **The A-list:** A list of prioritized device guidance documents the FDA intends to publish during FY2023.
- **The B-list:** A list of device guidance documents the FDA intends to publish as resources permit during FY2023.
- **Retrospective review list:** A list of final guidance documents issued in 1983, 1993, 2003, and 2013.

On this page:

- A-list
- B-list
- Retrospective review list for 1983, 1993, 2003, and 2013
- How to comment on these guidance lists or a specific guidance

A-List: Prioritized Guidance Documents that CDRH Intends to Publish in FY2023

Final Guidance Topics

- Remanufacturing of Medical Devices
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued

https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023

Upcoming 2023 Guidance

- **A – List:**
  - Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
  - Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) 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 Device Software Functions
  - Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program
  - Breakthrough Devices Program (revised)
  - Electronic Submission Template for De Novo Request Submissions (Draft)
- **B – List:**
  - Marketing Submission Recommendations for A Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Key Messages

- Determine the correct level of regulatory oversight for your software function
  - Familiarize yourself with new Guidance documents
  - Utilize new Digital Health informational pages and tools
- Start using eSTAR as it will be mandatory beginning on October 1, 2023.
- Keep up to date on regulations as changes are coming.

Extra Resources

- RQM+ Knowledge Center
  - RQM+ Live: Device Advice PodCast
  - Blogs
  - Webinars

Webinars

Common FDA and Notified Body Software Deficiencies and How to Avoid Them

RQM+ Live!

RQM+ Live! #61 — Medical Device Software: Top Deficiencies and Requests for Additional Info from FDA and Notified Bodies

Technical Briefs

How to Submit FDA CDRH Submissions Online

Thank You

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