

2017 IPAC-RS/ISAM Joint Workshop  
New Frontiers in Inhalation Technology

# FDA CDRH perspective on new technologies in inhaler products

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# Agenda

- Digital Health
- Innovation
- Mobile Medical Apps
- Software Modifications

# **Digital Health – a convergence of people, information, technology and connectivity in healthcare**

The word cloud illustrates the interconnected nature of digital health, showing how it integrates various sectors like consumer behavior, medical technology, and pharmaceuticals. Key themes include the shift towards digital solutions for healthcare delivery, the collection and analysis of patient data, and the use of technology to improve patient outcomes and engage consumers.

# Why do we talk about it?

- Transforming society
  - Cell phone usage
    - 77% of US adults have smartphone\*
    - Phone ownership
  - Broadband availability
    - 73% of American adults have a high-speed broadband connection at home\*\*
  - Technology ownership
    - >75% own a computer\*
  - Information Sources
    - Social Media
    - Online publications

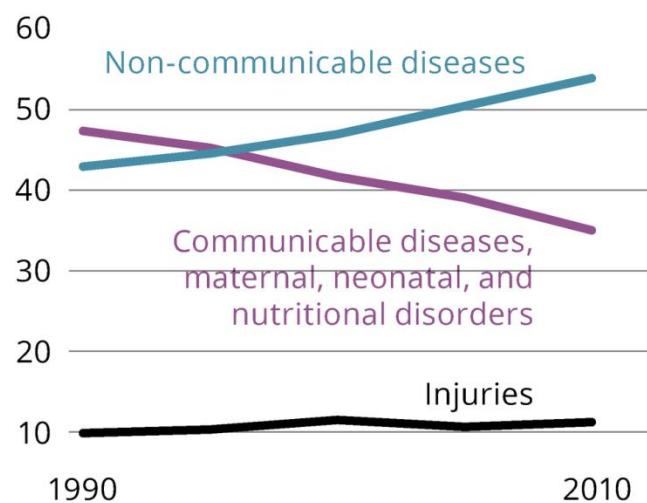
	Any cellphone	Smartphone	Cellphone, but not smartphone
Total	95%	77%	18%
Men	96%	78%	18%
Women	94%	75%	19%
White	94%	77%	17%
Black	94%	72%	23%
Hispanic	98%	75%	23%
Ages 18-29	100%	92%	8%
30-49	99%	88%	11%
50-64	97%	74%	23%
65+	80%	42%	38%
Less than high school graduate	92%	54%	39%
High school graduate	92%	69%	23%
Some college	96%	80%	16%
College graduate	97%	89%	8%
Less than \$30,000	92%	64%	29%
\$30,000-\$49,999	95%	74%	21%
\$50,000-\$74,999	96%	83%	13%
\$75,000+	99%	93%	6%
Urban	95%	77%	17%
Suburban	96%	79%	16%
Rural	94%	67%	27%

\* <http://www.pewinternet.org/fact-sheet/mobile/>

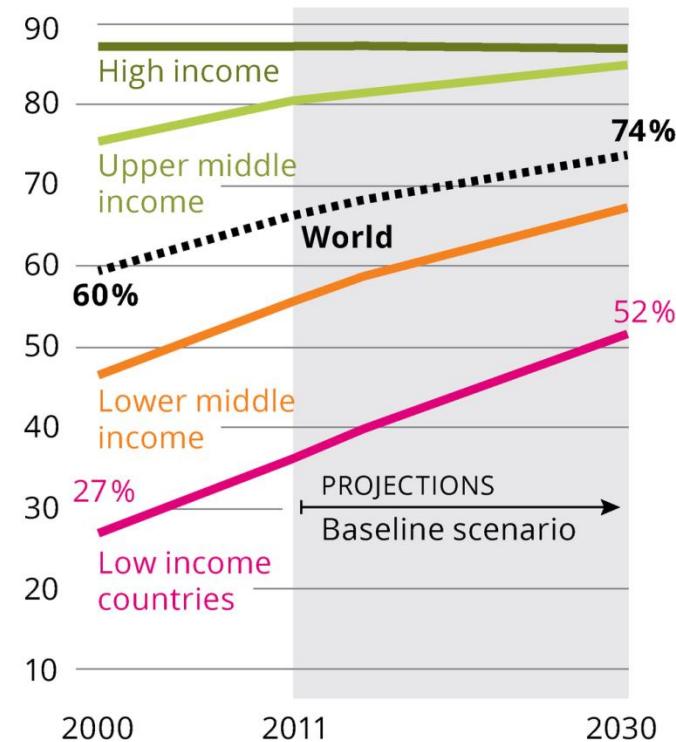
\*\* <http://www.pewresearch.org/data-trend/media-and-technology/internet-penetration/>

# Disease Burden

Loss of healthy life years  
(in percentage of total DALY)



Deaths related to non-communicable diseases (in percentage of total deaths)



# FDA Mission

- The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.
- FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.
- FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

# CDRH

- In keeping with our mission, the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.
- We seek to continually improve our effectiveness in fulfilling our mission by planning strategically and regularly monitoring our progress.

# Innovation

- In Indications
  - New device, new treatment, new diagnostic, new patient population
- In Implementation
  - Smaller, battery powered, user interface, new platform
- Both can be facilitated by digital technology

# Digital Health Technologies

- Have potential to:
  - Get to market faster
  - Provide innovative care paradigms
  - Support chronic disease management



# CDRH DIGITAL HEALTH

# CDRH Digital Health Big Picture

- Foster trust in innovative technologies as an enabler of a new healthcare paradigm
- Enable “patient centered” public health as digitization touches every aspect of health care
- Adapt regulatory science to evolving technological landscape



# Foundational Policies



# Mobile Medical Applications (MMA) Guidance Document

Final Published Feb 9, 2015

Available here: <https://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>

# Mobile Medical App

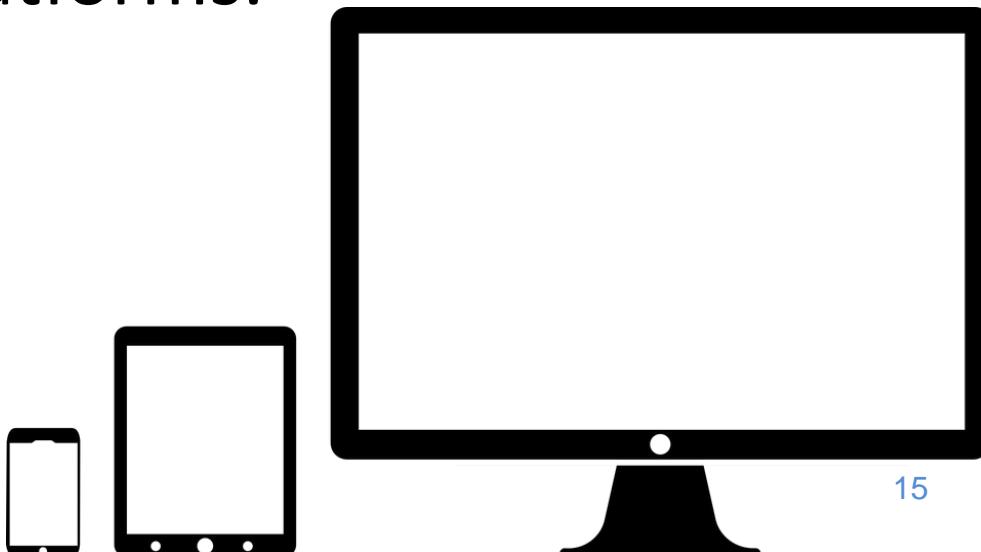
A “Mobile **Medical** App” is a software application that can be executed (run) on a mobile platform (i.e. mobile app) that meets the definition of device, and is either intended to:

- be used as an accessory to a regulated medical device; or
- transform a mobile platform into a regulated medical device.

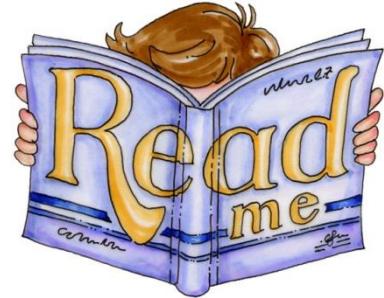


# Mobile Platform

- Mobile Platforms are defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature.
- Examples include laptops, smart phones, tablet and other portable platforms.



# MMA's Intended Use

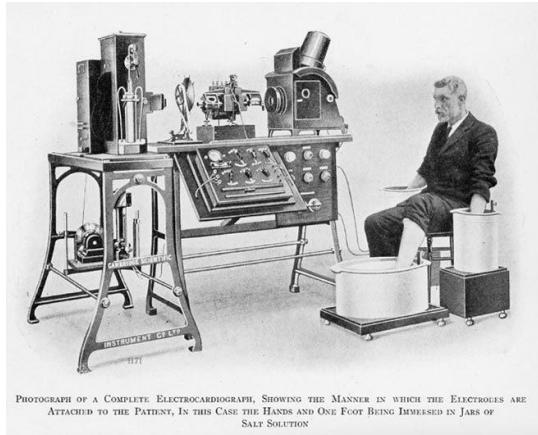


The intended use of a mobile app determines whether it meets the definition of a device. As stated in 21 CFR 801.4, intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives.



In general, if a mobile app is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, **regardless** of the platform on which it is run.<sup>16</sup>

# Functionality focused (ECG device)



PHOTOGRAPH OF A COMPLETE ELECTROCARDIOGRAPH, SHOWING THE MANNER IN WHICH THE ELECTRODES ARE ATTACHED TO THE PATIENT, IN THIS CASE THE HANDS AND ONE FOOT BEING IMMERSED IN JARS OF SALT SOLUTION



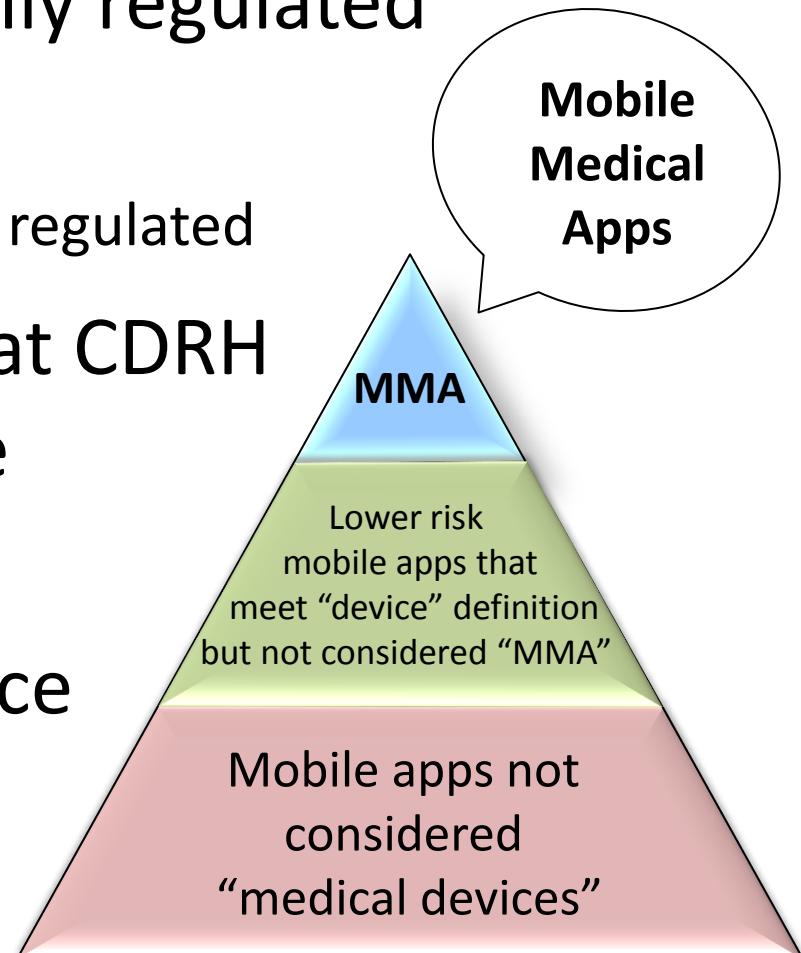
# Regulatory Approach

- CDRH applies regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended.
- Manufacturers of MMAs are expected to follow the Quality System regulation (which includes good manufacturing practices).
- Manufacturers must meet the requirements associated with the applicable device classification. If the mobile medical app, on its own, falls within a medical device classification, its manufacturer is subject to the requirements associated with that classification.

# Medical Mobile Apps Summary



- Focuses only on traditionally regulated functionality
  - Cleared, approved or otherwise regulated
- Identifies types of apps that CDRH does not intend to enforce regulatory requirements
- Clarifies what is not a device
  - (Outside of CDRH's Jurisdiction)

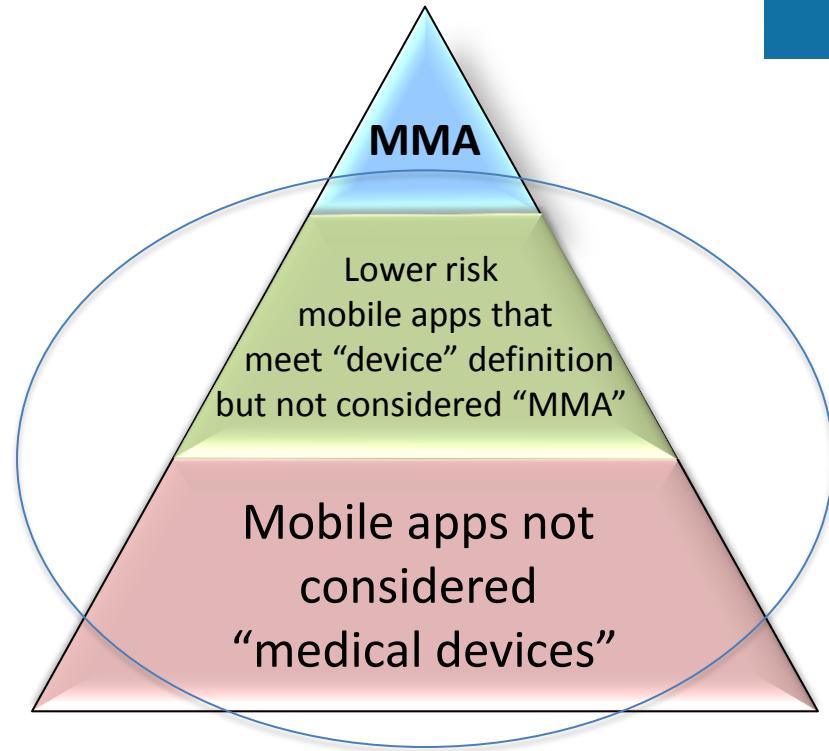


# What does Enforcement Discretion mean?



CDRH does not intend to enforce requirements under the FD&C Act for Mobile applications that are low risk even if they meet the definition of a device.





# MOBILE APPS THAT ARE NOT THE FOCUS OF CDRH OVERSIGHT

# Provide or Facilitate Supplemental Clinical Care



**MMAs that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment**

- Examples include:
  - Mobile apps that help patients with diagnosed psychiatric conditions maintain their behavioral coping skills by providing a “Skill of the Day”
  - Behavioral technique or audio messages that the user can access when experiencing increased anxiety

# Tools for Tracking and Trending

FDA

Mobile apps that provide patients with simple tools to organize and track their health information

- Log, track, or trend health events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state)
- Share this information with their health care provider as part of a disease-management plan

# Perform Simple Calculations

FDA

Mobile apps that perform simple calculations routinely used in clinical practice

- Examples include:
  - Body Mass Index (BMI)
  - Total Body Water / Urea Volume of Distribution
  - Glasgow Coma Scale score
  - APGAR score
  - NIH Stroke Scale

# MDDs

**Apps that are intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device**

- Examples include:
  - Transfer of information to an EHR
  - Encryption of data
  - Storage of medical device data on a cloud server

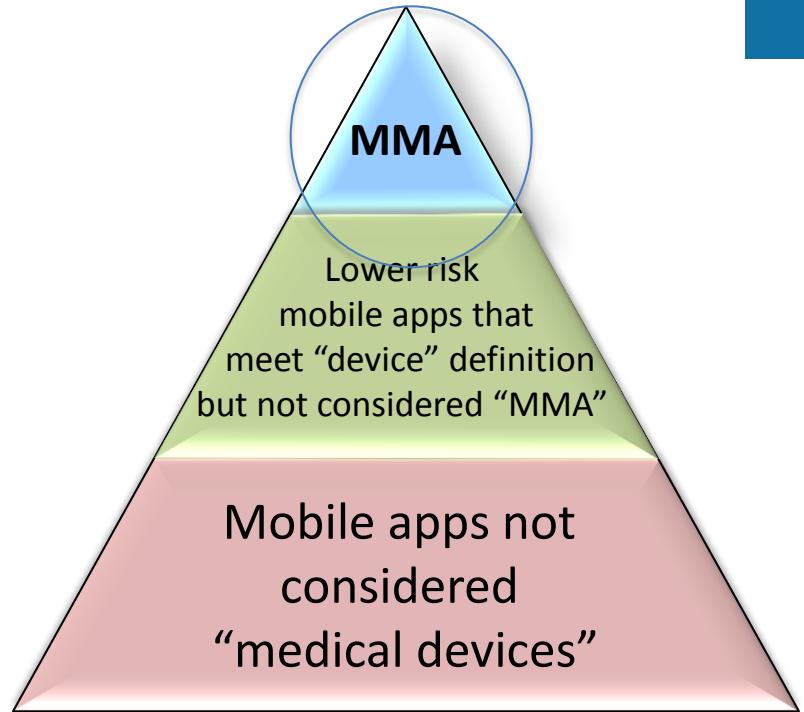
# MDDs and the 21 Century Cures Act

FDA

Section 3060 (a)(o)(1)(D) amends the Food, Drug, and Cosmetic Act (FDCA) to exclude from the definition of a “device” software intended

*“for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings;*

**Following the 21st Century Cures Act products that meet the definition of MDDs will NOT be considered medical devices**



## MMA<sup>s</sup> UNDER CDRH'S OVERSIGHT

# MMMAs that are Extensions of a Medical Device



**Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device data.**



For example an app that provides the ability to control inflation and deflation of a blood pressure cuff through a mobile platform.

# MMAAs that Transform the Mobile Platform into a Medical Device



**MMA that transforms 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.**

Examples include:

- ECG electrodes that connect to a mobile platform to measure, store, and display ECG signals
- a mobile app that uses sensors (internal or external) on a mobile platform for creating electronic stethoscope function

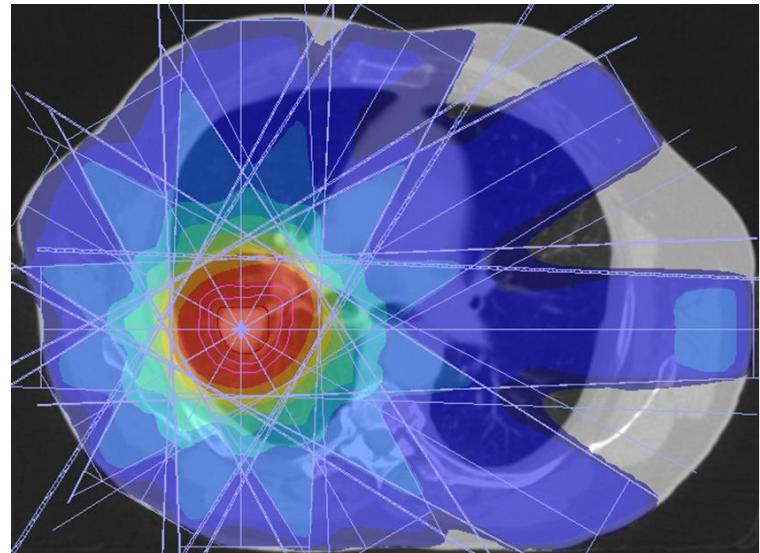


# MMAAs that provide Analysis, Diagnosis and Treatment



**MMA that performs patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.**

- For example apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; or apps that detects Atrial Fibrillation.



# **Deciding When to Submit a 510(k) for a Software Change to an Existing Device**

Draft Published: Aug 8, 2016  
**NOT YET FINALIZED**

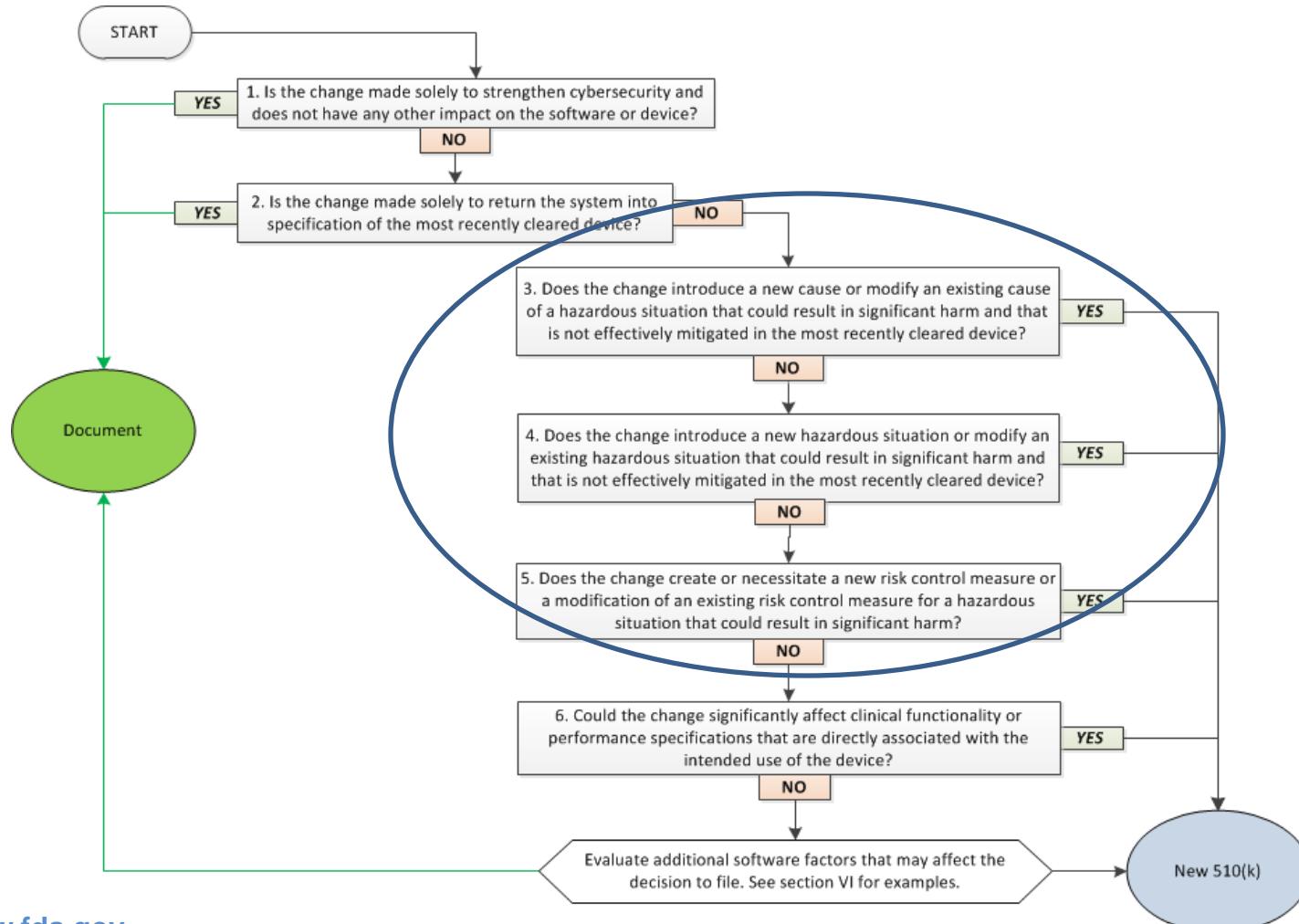
# Overview

- Specific to software changes done to 510(k) cleared devices
- Specifies framework for determining if changes require a new 510(k)

# Quality System Regulation

- 21 CFR 820.30(i) *Design changes* - Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.
  - Robust documentation is helpful to both FDA and manufacturers

# Decision making process



# Q1 & Q2

*If answer is **yes** to either of these questions, then a new 510(k) is not likely required.*

Q1: Is the change made **solely** to strengthen cybersecurity and **does not have any other impact** on the software or device?

Q2: Is the change made **solely** to return the system into specification of the **most recently cleared device**?

# Risk Questions

*If answer to any of these questions is yes, then a new 510(k) is likely required.*

Q3: Does the change introduce a new cause or modify an existing cause of a hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?

Q4: Does the change introduce a new hazardous situation or modify an existing hazardous situation that could result in significant harm and that is not effectively mitigated in the most recently cleared device?

Q5: Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?

# Question 6

*If answer to this questions is yes, then a new 510(k) is likely required.*

Q6: Could the change significantly affect **clinical functionality** or **performance specifications** that are directly associated with the intended use of the device?

# Important

This draft guidance is a proposal that has been released for public comment and has not been finalized.