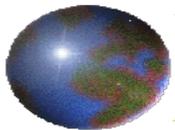


# *Medical Device Software*

*Bakul Patel*

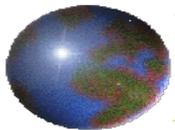
*Senior Policy Advisor*



# Overview

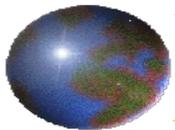
- Medical devices and software
- Oversight principles and Current approach
- Trends, Challenges and opportunities
- Addressing challenges





# Definition of Device

- ❖ SEC. 201. [321] For the purposes of this Act –
- ❖ (h) The term "device" ... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
  - recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
  - 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
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal 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 any of its principal intended purposes.



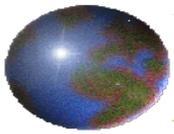
# Medical Device

The Section 201(h) of the Food, Drugs and Cosmetics Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.

- ❏ **As simple as a tongue depressor or a thermometer**

- ❏ **As complex robotic surgery devices**





# *A risk based approach ...since 1976*

## Increasing Risk

Classification determines extent of regulatory control (Risk Based)

### Class I

- General Controls

### Class II

- General controls
- Special controls

### Class III

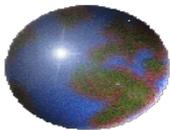
- General controls
- Premarket approval (PMA)

#### General Controls

- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

#### Special Controls (addressing Risk)

- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)



# Increasing use of software

## 1 The accelerating pace of change ...



## 2 ... and exponential growth in computing power ...

Computer technology, shown here climbing dramatically by powers of 10, is now progressing more each hour than it did in its entire first 90 years

### COMPUTER RANKINGS

By calculations per second per \$1,000



**Analytical engine**  
Never fully built, Charles Babbage's invention was designed to solve computational and logical problems



### Colossus

The electronic computer, with 1,500 vacuum tubes, helped the British crack German codes during WW II



### UNIVAC I

The first commercially marketed computer, used to tabulate the U.S. Census, occupied 943 cu. ft.

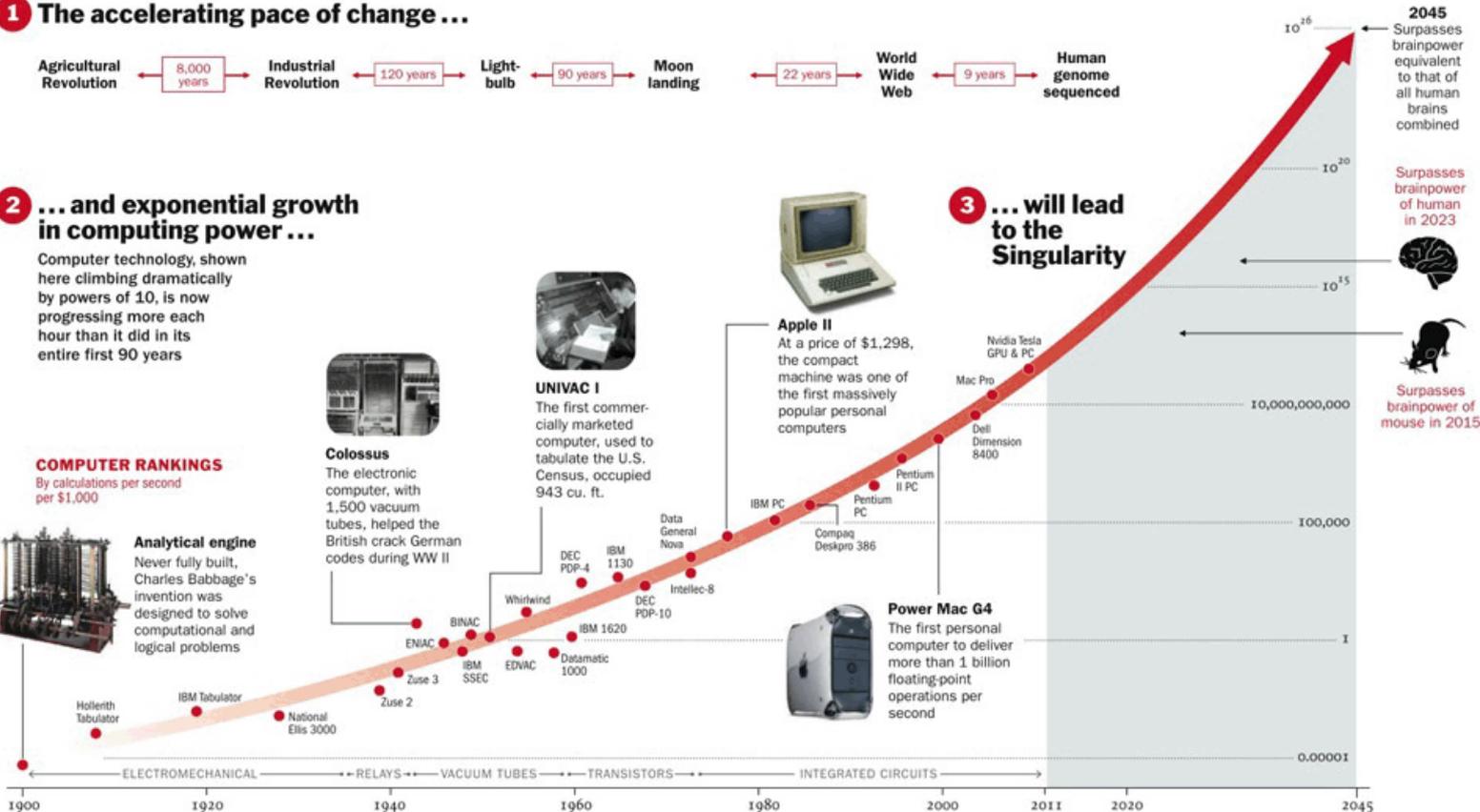


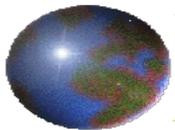
**Apple II**  
At a price of \$1,298, the compact machine was one of the first massively popular personal computers

## 3 ... will lead to the Singularity

### Power Mac G4

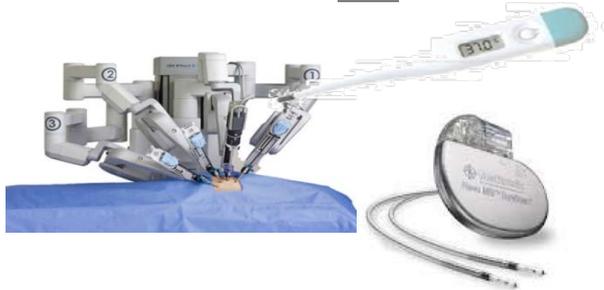
The first personal computer to deliver more than 1 billion floating-point operations per second





# Types of Medical Device Software

Software in a device



in

as

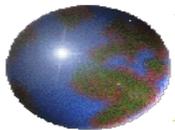
U

Software as a device

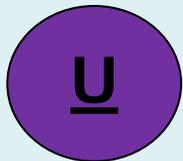


Software that is Used in the manufacturing process of a device





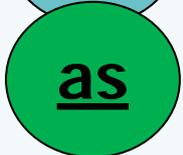
# Regulatory focus



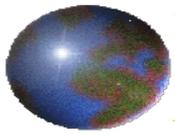
Oversight primarily to assure quality of product  
(focus more important for class III devices)



-Premarket oversight on higher risk products  
(class II and Class III)



-Post market surveillance



# *Classifications depend on..*

in

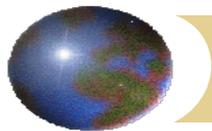
as

## ✦ What does it do? (engineering view)

- ✦ Calculates doses
- ✦ Displays medical images
- ✦ Controls treatment timing
- ✦ Collects user input

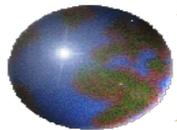
## ✦ How can it be used? (clinical view)

- ✦ to formulate treatment plans
- ✦ to recommend additional tests
- ✦ to diagnose the presence of tumors
- ✦ to calculate insulin dose



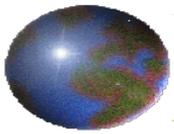
# *Principles of oversight control*

- ✚ Regulations relies on each manufacturer to
  - ✚ Understand the role of software in their products
  - ✚ Understand the risk of software in their products
  - ✚ Follow development processes that are best suited for their organization and their product
  - ✚ Maintain vigilance over their product once in the market

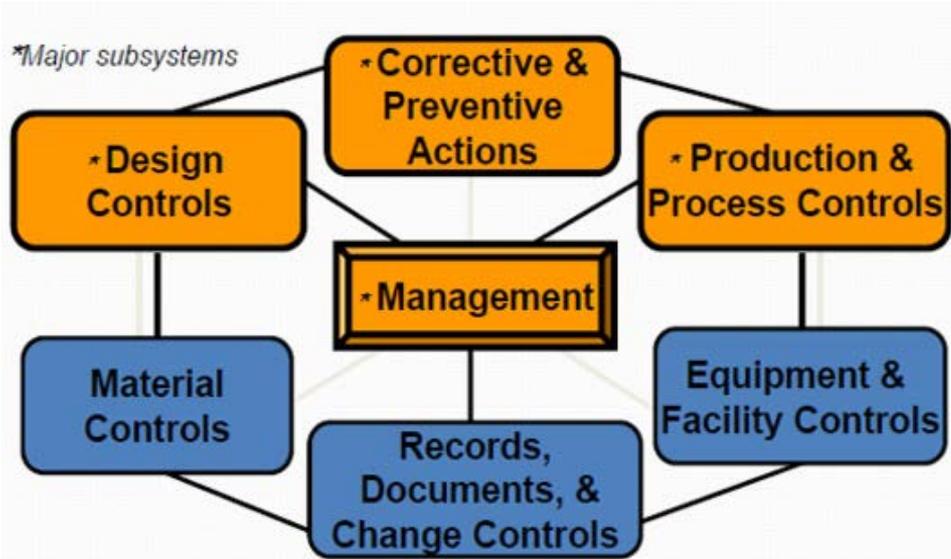


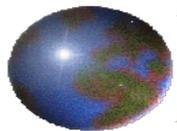
## A “*Life cycle*” approach

- ✚ Does not recommend any specific life cycle model or any specific technique or method, it does recommend that software validation and verification activities be conducted throughout the entire software life cycle.  
[GPSV]



# Quality systems + standards



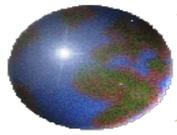


# *Control for software focuses on..*

## ✦ Design process

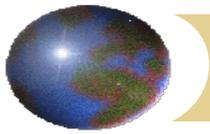
- ✦ Systematic risk assessment is expected as an integral part of design and development
- ✦ Products implement with principles of good design and development practices

## ✦ Adequately validating the solution



# Software Validation

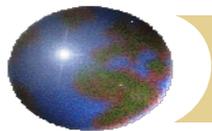
- ⊕ Part of the design validation for a finished device
- ⊕ FDA considers software validation to be "*confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.*"
- ⊕ In practice, software validation activities may occur both during, as well as at the end of the software development life cycle to ensure that all requirements have been fulfilled.



# *The Sum of the Parts*

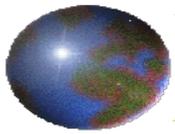
- ✦ A conclusion that software is validated is highly dependent upon comprehensive software testing, inspections, analyses, and other verification tasks performed at each stage of the software development life cycle.

**[<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf>]**



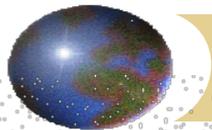
# *FDA software guidance*

- ✚ General Principals of Software Validation-
  - ▣ What to *do*
- ✚ Off-The-Shelf Guidance
  
- ✚ Pre Market Guidance (this one from 2005)
  - ▣ What to *submit*

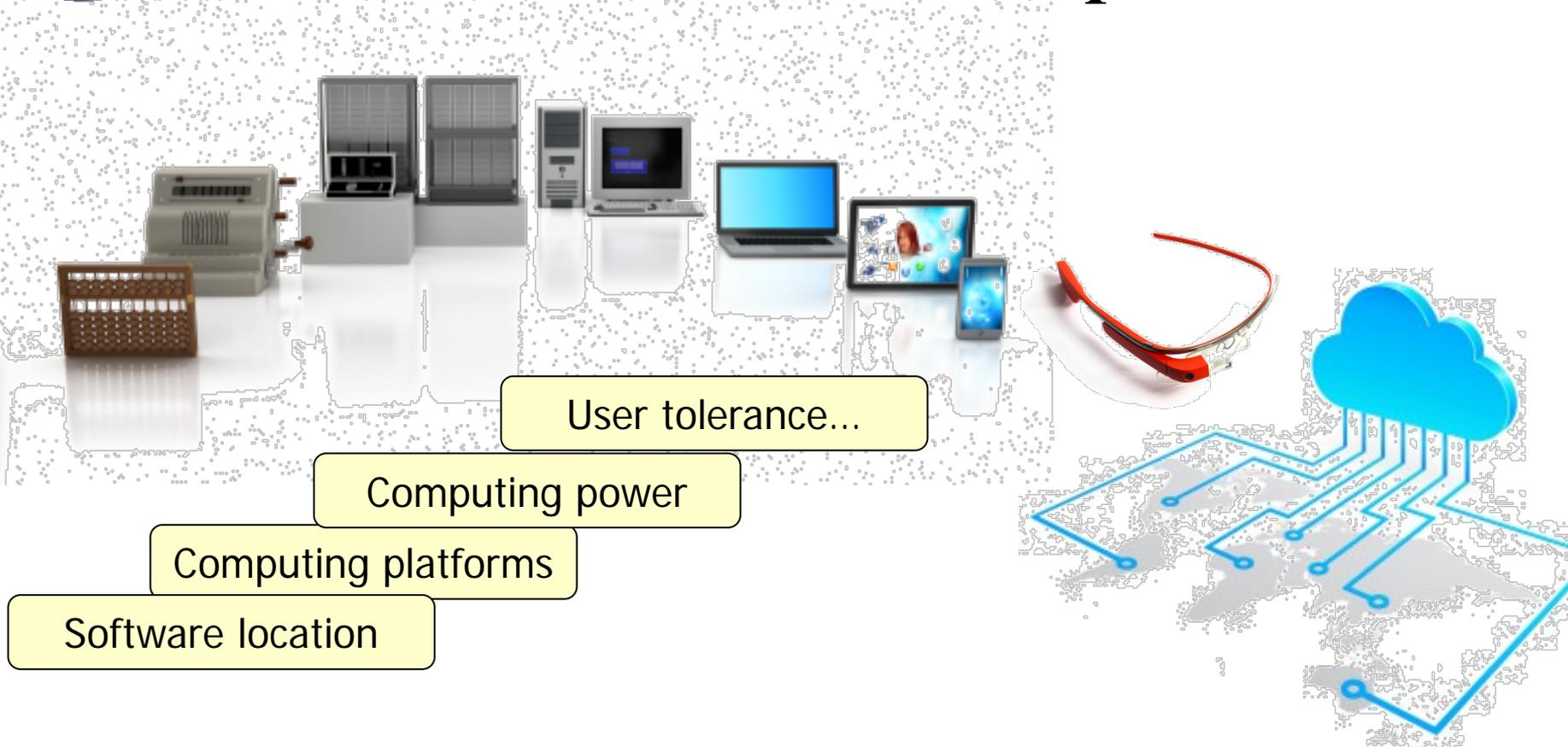


# *Contents of premarket review*

- ✦ Level of Concern
- ✦ Software Description
- ✦ Device Hazard Analysis
- ✦ Software Requirements Specification
- ✦ Architecture Design Chart
- ✦ Software Design Specification
- ✦ Traceability Analysis
- ✦ Software Development
- ✦ Environment Description
- ✦ Verification and Validation Documentation
- ✦ Revision Level History
- ✦ Unresolved Anomalies (Bugs or Defects)



# Trends and next steps

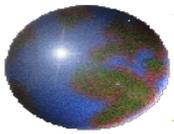


User tolerance...

Computing power

Computing platforms

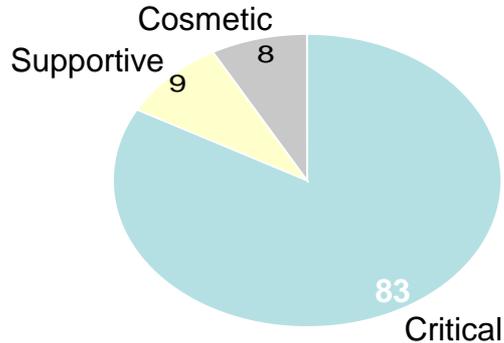
Software location



# Software has become increasingly important

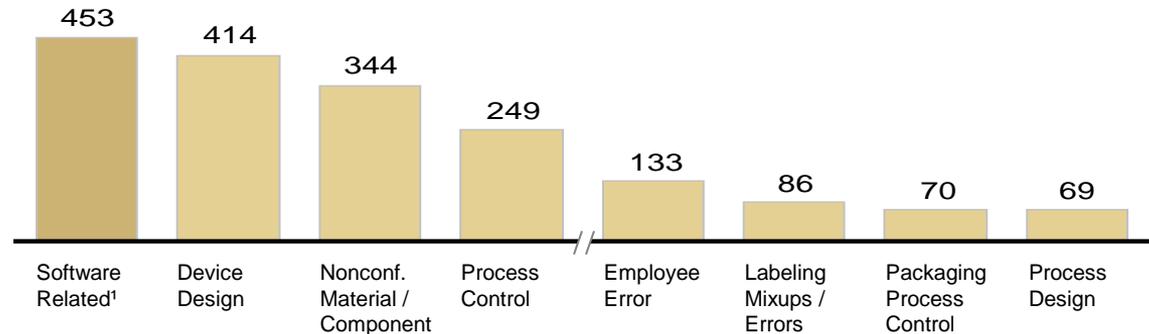
## Software is important to medical device functionality

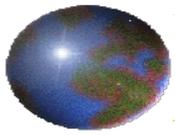
Percent (N=88)



## Software-related problems have become the most cited cause of medical device recalls

Total recalls (cumulative over FY10 – FY12)

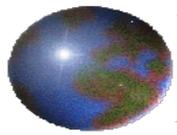




# Rapidly Evolving Landscape

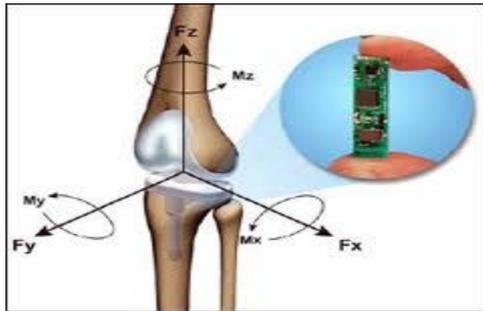
- ✦ Most medical devices rely heavily software
- ✦ Software development practices are evolving
- ✦ Changes to software are easy and more frequent
- ✦ Connectivity of devices have lead to new risks
- ✦ Diagnostics and analytics rely heavily on software

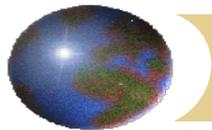




# Current concepts challenged

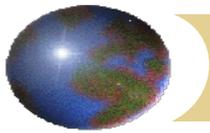
- ✦ Establishments - as we know for traditional device do not translate clearly to a virtual software world
- ✦ Finished goods - devices are finished by the consumer – by relying on consumer to provide portions of the device.
- ✦ Distribution – distribution of physical product no longer valid (for e.g., internet cloud based)





# *Adapting oversight by*

- ✚ Clarifying focus of regulatory oversight
  
  
  
  
  
  
  
  
  
  
- ✚ Considering technology, and current practices



# Smart Regulatory Approach

Platform independent

Promote innovation

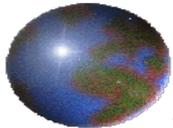
Protect patient safety

Promote patient engagement

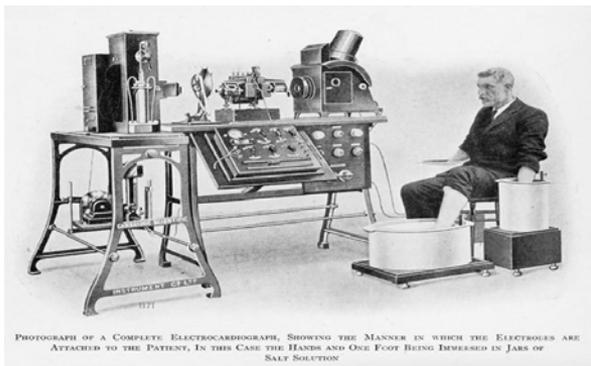
Functionality focused

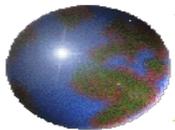
Narrowly tailored

**Risk based**



# Functionality focused (EKG machine)



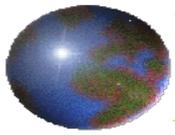


# Addressing challenges

## interoperability

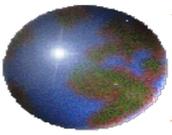


## Device security



# *US-FDA software documents*

- ❖ 1989 Draft software policy (withdrawn in 2005)
- ❖ 1991 Pre-market software guidance
- ❖ 1999 Off-the-Shelf Software Guidance
- ❖ 2002 General Principles of Software Validation
- ❖ 2005 Cybersecurity Software Guidance -- OTS
- ❖ 2011 Medical Device Data System Rule
- ❖ 2013 RF wireless devices – Final guidance
- ❖ 2013 Draft: Cybersecurity premarket guidance
- ❖ 2013 Recognized Interoperability and cyber security standards
- ❖ 2013 Mobile medical apps – Final guidance



# Mobile medical apps (MMA)

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

**Enforcement Discretion**

**focus of oversight**



Mobile apps that meet "device" definition that are either intended

- To be used as an accessory to already regulated medical device,

**or**

- To transform a mobile platform into a regulated medical device.

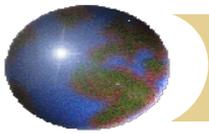
**MMA**

Lower risk mobile apps that meet "device" definition but not considered "MMA"

Mobile apps not considered "medical devices"

**No regulatory requirements**





# ?? Questions/Discussion ??

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