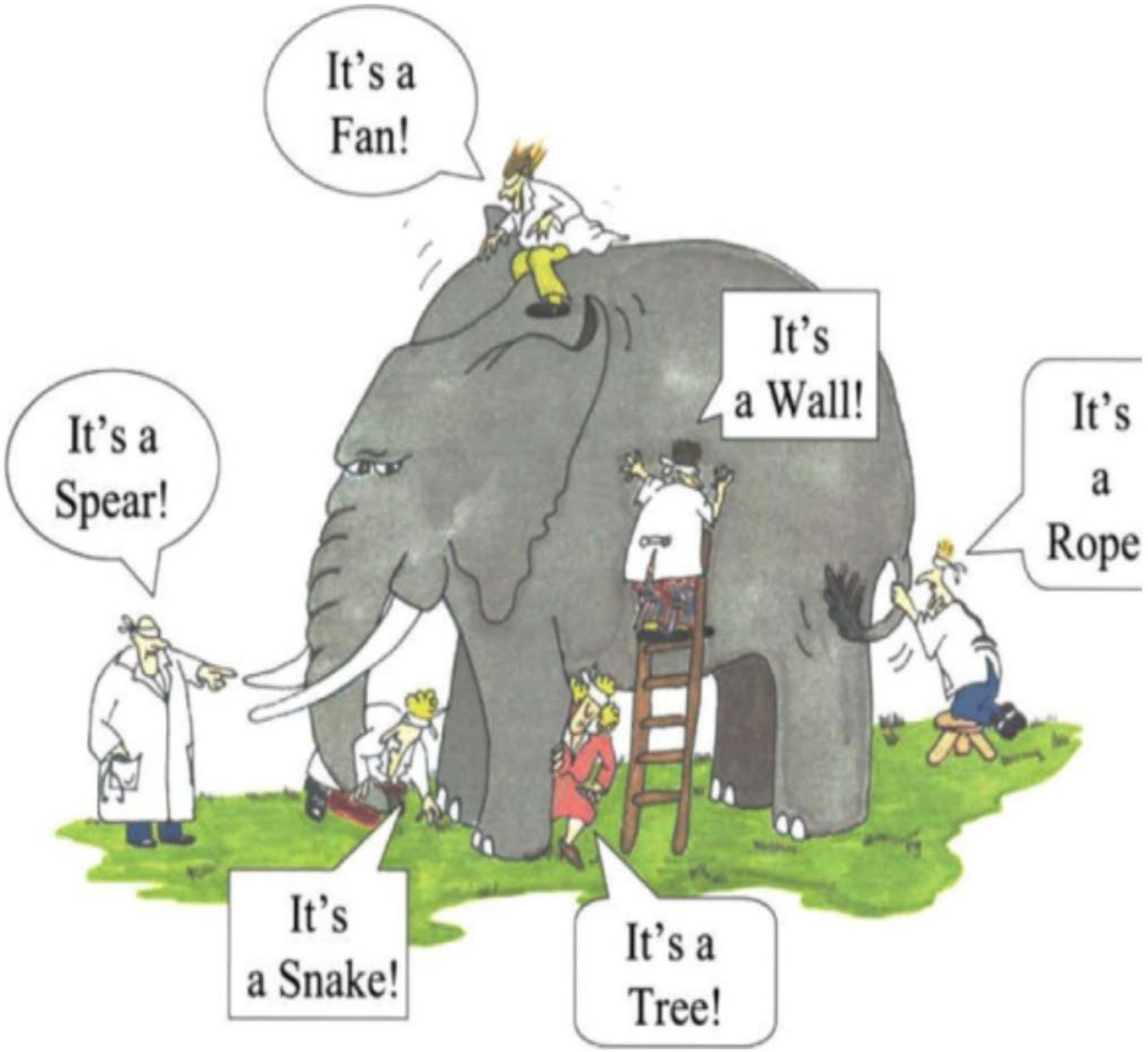
FDA Regulation of the Internet of Things (IoT)

David W Feigal, Jr., MD MPH

May 16, 2018

Regulatory Oversight



FDA: Computing and Software

Is the IoT in FDA's remit?

Definition of a Devices (from the FDCA)

The term “device" means:

Instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is -

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 …

Same words as “drug”

Definition of a Devices (from the FDCA) *continued*

The term “device" means:

… 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.

FDA regulates if the device …

Intends

… diagnose, prevent, cure, mitigate, treat

… disease or other condition

… affect the structure or function of the body

FDA and Computers and Software

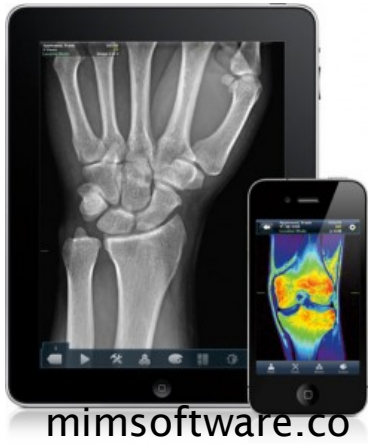
FDA Got Off to a Slow Start

- Unwilling to endorse standard software (*tower of Babel*)
- "Part 11" electronic signature -- unintended consequences (the terrors of *validation*)
- Approval of static systems (which helpfully evolved to approval of software development and change *processes*.)
- Risk based regulation concept applied to software was difficult
  - How is risk different for consumer use vs health care professional use
- Y2K
- Wireless - Interference between devices

Medical Device Data Systems (MDDS) and Mobile Medical Aps: *Evolving FDA Regulation*

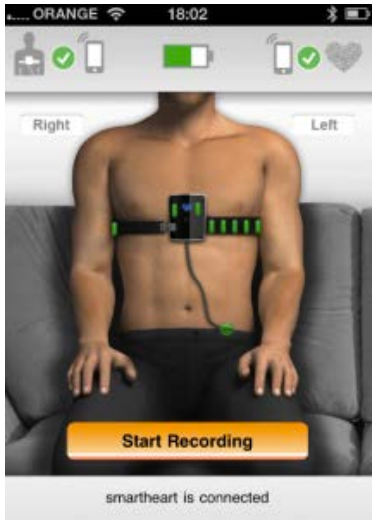
Mobile Medical Aps

applied-nanodetectors.com



mimsoftware.com

Remote monitoring of people in the home-
Evolving timeline



FDA clears Smartheart mobile ECG device
Apr 17, 2012
http://mobihealthnews.com/17031/fda-clears-smartheart-mobile-ecg-device/

mHealth & Mobile Medical Aps- FDA

On February 15, **2011**, FDA issued a regulation down-classifying Mobile Medical Data System (MDDS) from Class III (high-risk) to Class I (low-risk). Class I devices are subject to general controls under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Reference: Medical Devices; Medical Device Data Systems Final Rule (76 FR 8637) (Feb. 15, 2011).

Since down-classifying MDDS in 2011, the FDA does not intend to enforce compliance with the regulatory controls that apply to MDDS devices, medical image storage devices, and medical image communications devices.

*Reference: FDA Updated the Medical Device Data Systems (MDDS), Medical Image Storage Devices, and Medical Image Communications Devices Guidance, issued February 9, **2015***

http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm401996.pdf

mHealth & Mobile Medical Aps- FDA

FDA MDDS Definitions

MDDS is a medical device intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

- Electronic transfer or exchange of medical device data.
  - For example, software that collects output from a ventilator about a patient's CO2 level and transmits the information to a central patient data repository.
- Electronic storage and retrieval of medical device data.
  - For example, software that stores historical blood pressure information for later review by a healthcare provider.

mHealth & Mobile Medical Aps- FDA

FDA MDDS Definitions *(continued)*

MDDS is a medical device intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

Electronic conversion of medical device data from one format to another in accordance with a preset specification.

For example, software that converts digital data generated by a pulse oximeter into a digital format that can be printed. Example, Alere Connect's MobileLink or HomeLink device.

Electronic display of medical device data.

For example, software that displays a previously stored electrocardiogram for a particular patient.

mHealth & Mobile Medical Aps- FDA

FDA Cleared Mobile Medical Applications
Last updated (June 6, 2013)

Device Name	Applicant	510(k) Number	Decision Date
RHYTHMSTAT XL	DATA CRITICAL CORP.	K971650	12/04/1997
MOBILE-PATIENT VIEWER	DATA CRITICAL CORPORATION	K011436	07/05/2001
MODIFICATION TO: POCKETVIEW ECG SOFTWARE	MICROMEDICAL INDUSTRIES, LTD.	K013311	01/03/2002
FREESTYLE TRACKER DIABETES MANAGEMENT SYSTEM	ABBOTT DIABETES CARE INC.	K020866	06/11/2002
TM2005 PERSONAL MEDICAL PHONE CENTER	CARD GUARD SCIENTIFIC SURVIVAL, LTD.	K024365	01/15/2003
SPECTRUM AND SPECTRUM WITH MASTER DRUG LIBRARY	SIGMA INTL.	K042121	08/26/2004
SD360 DIGITAL RECORDER/SD360 HOLTER DIGITAL RECORDER	NORTHEAST MONITORING, INC.	K041901	08/31/2004
AIRSTRIP OB	MP4 SOLUTIONS, LP	K042082	01/21/2005
VEO MULTIGAS MONITOR FOR POCKET PC, MODEL 400221	WEISSBURG ASSOCIATES	K051857	09/15/2005
DATEX-OHMEDA S/5 WEB VIEWER, DATEX-OHMEDA S/5 POCKET VIEWER AND DATEX-OHMEDA S/5 CELLULAR VIEWER WITH L-WEB04 SOFTWARE	GE HEALTHCARE	K052975	01/20/2006
PILL PHONE	VOCEL	K060298	03/29/2006

This list was based on FDA's original interpretation prior to 2/9/15 of cleared applicable devices

mHealth & Mobile Medical Aps- FDA

MDDS Draft Guidance has the following modifications

- MDDS and Mobile Medical Aps that meet the definition of a Medical Device Data System (MDDS) (21 CFR 880.6310) and are subject to class I requirements (general controls).
  - Class I are the lowest risk devices with the fewest requirements and generally no premarket submission. Class I general controls include these basics: adequate design controls, registration, device listing, adverse event reporting, and corrections and removals.
  - Requiring general controls sufficiently manages the risks for mobile medical apps that are used as a secondary display to a regulated medical device and are not intended to provide primary diagnosis or treatment decisions (i.e., mobile medical apps that meet the MDDS definition).

mHealth & Mobile Medical Aps- FDA

FDA is trying to stay current with the trend of Mobile Aps (Are they going too far for Safety and Efficacy?)
MDDS Draft created the following modifications
(ISSUED February 9, 2015),

FDA does not intend to enforce compliance with the regulatory controls that apply to the following devices:

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.

This means that for MDDS devices, FDA does NOT intend to enforce compliance with the regulatory controls, including registration and listing, premarket review, postmarket reporting and quality system regulation for manufacturers of these types of devices.

These devices are exempt from premarket notification with some limitations.

Device Definition Changed in 2017

The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) 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 —

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) 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

(3) 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.

The term 'device' does not include software functions excluded pursuant to section 520(o).

Excluded Software

(o) Regulation of Medical and Certain Decisions Support Software—

(1) The term device, as defined in section 201(j), shall not include software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B)for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

Note: no structure / function

Excluded Software

(o) Regulation of Medical and Certain Decisions Support Software—

(1) The term device, as defined in section 201(j), shall not include software function that is intended—

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

I.E., Computer Aided Diagnosis is still regulated

Excluded Software

(o) Regulation of Medical and Certain Decisions Support Software—

(1) The term device, as defined in section 201(j), **shall not include** software function that is intended—

(D) 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; or

I.E., description is OK – analysis is not

Excluded Software

(o) Regulation of Medical and Certain Decisions Support Software—

(1) The term device, as defined in section 201(j), shall not include software function that is intended—

(E) Unless the function is 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, for the purpose of—

Double Negative

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling such health care professional to independently review the basis for such recommendation 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.

FDA Guidance

file:///D:/Pt/D/FDA%20Guidance/Clinical%20decision%20making%202017%20UCM587819.pdf

Contains Nonbinding Recommendations

Draft - Not for Implementation

Clinical and Patient Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: December 8, 2017

You should submit comments and suggestions regarding this draft document within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director at (301) 796-6900 or email DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010. For questions about this document regarding CDER-regulated products, contact Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

Decision Support for Patients

The law only exempts decision support software for health care professionals … i.e., all patient decision support software would still be regulated …

Except ..

FDA will apply 'enforcement discretion' when the patient decision support software meets the same criteria as healthcare professional software.

Viz.ai LVO Stroke System

Identify LVOs Automatically

Deep learning algorithms automatically analyze CTA images to identify suspected large vessel occlusion (LVO) strokes.

Notify Specialists Directly

Notifications for suspected LVOs are sent to specialists who can view the patient's CTA images on a mobile device. Median time to the notification is under 6 minutes.[1]

Transfer Patients Promptly

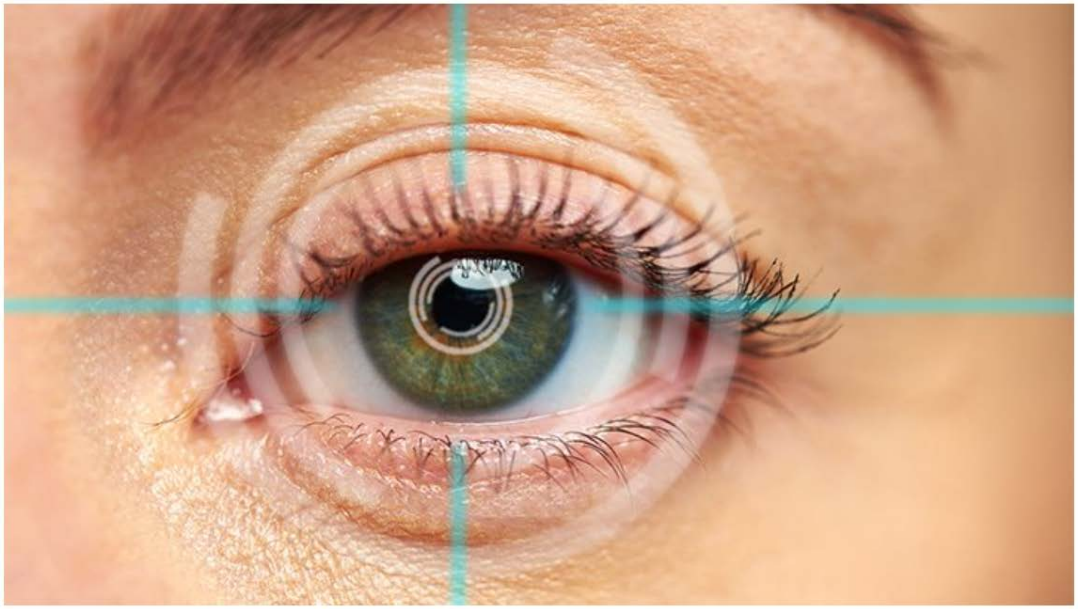
Specialists can initiate transfers to interventional centers using the care team communication and transport optimization platform that is integrated with emergency and transportation services.

Treat with IV tPA & Thrombectomy

Earlier notifications can decrease the time to treatment by empowering specialists and physicians to intervene in acute ischemic stroke by providing IV tPA and endovascular treatment sooner.[2]

FDA Approves Marketing of Device That Can Help Detect Irreversible Diabetic Retinopathy

The device, called the IDx-DR, may help increase access to diagnostic tools for diabetes-related vision loss, but only if physicians decide to adopt it in their practice.

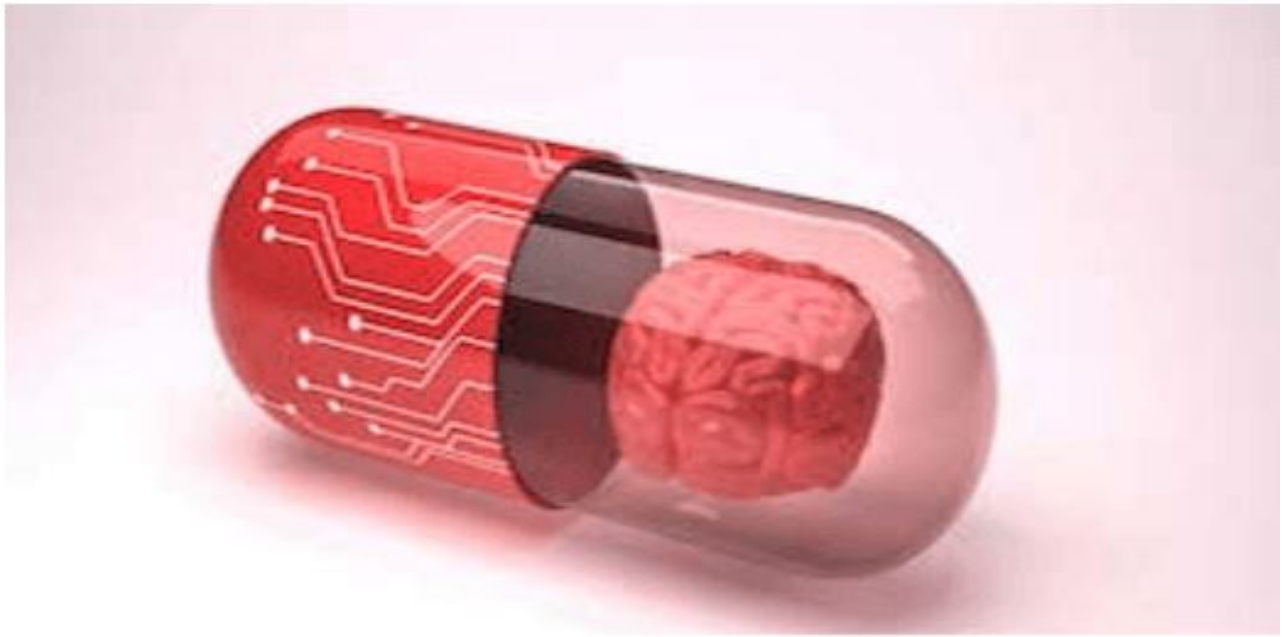


Diabetic retinopathy is one of the most preventable causes of blindness, but poor access to specialists who can screen for the disease poses a barrier to care. iStock

April 16, 2018

A medical device that uses artificial intelligence (AI) to detect vision loss in people with type 2 diabetes is now available to the general public after the Food and Drug Administration (FDA) fast-tracked its approval earlier this year.

FDA and the Smart Pill



FDA and Computers and Software

FDA 2018

- It's not about wireless or the internet
  - No regulation of Bluetooth / Internet *per se*
- FDA relies upon *consensus standards*
- *Process* is more important than *software code*
- Risk based regulation concept applied to software:
  - It's the *claim* that makes it a medical device
  - It's the *information* that determines the *risk*
  - It's the *information* that delivers the *benefit*


THE
Innovation
agenda