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FDA Guidance/Regulations Regarding Medical Devices

State Bar of Michigan Health Law Section

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FDA Hot Topics

- Product quality
  - Inspections
  - Corrective actions
  - Recalls
- Medical Device Reporting
- Changes to 510(k)s –
  - Note to file
  - New 510(k) submission
- Use of Big Data
- Digital Health and Cybersecurity
- Mobile Medical Apps
- Off-label use
- Sterilization
- Reimbursement issues
- Reprocessing of Devices
- Increased use of human factors
- Use of 3-D Printing and Imaging
- Biocompatibility

- Other hot areas
  - Pricing
  - Vaping
  - CBD

Focus Areas: "Medical Devices" & FDA's Regulatory Framework

- What is a "Device"?
- Differentiating medical devices from drugs and non-medical devices
- The 3 risk-based classes of medical devices
- Overview of FDA regulation of devices & paths to market for devices
- Understanding combination products: definitions, processes, strategies & implications
- Working with FDA's Center for Devices & Radiological Health
- Office of Regulatory Affairs realignment

Discussion Agenda

- FDA device law milestones
- Key statutory product definitions
- Distinguishing medical devices from drugs and not "devices"
- Device lifecycle regulation
- FDA's 3 device classes, general controls & special controls
- FDA Pathways to Market for Devices: Typical Approaches
- Additional Paths to Market & Pre-market Strategies
- Remember … the "R" in CDRH is its own regulatory framework
- Understanding combination products: Definitions, processes, strategies & implications
- Software as a Medical Device
- Working with FDA's Center for Devices & Radiological Health
- Understanding FDA's Enforcement Tools

Postmarket Regulation: Key Areas

- Advertising and Promotion
- QSR (Quality System Regulation)
- Medical Device Reporting
- Recalls, Removal, and Corrections
- Postmarket Studies

FDA Medical Device Law Milestones

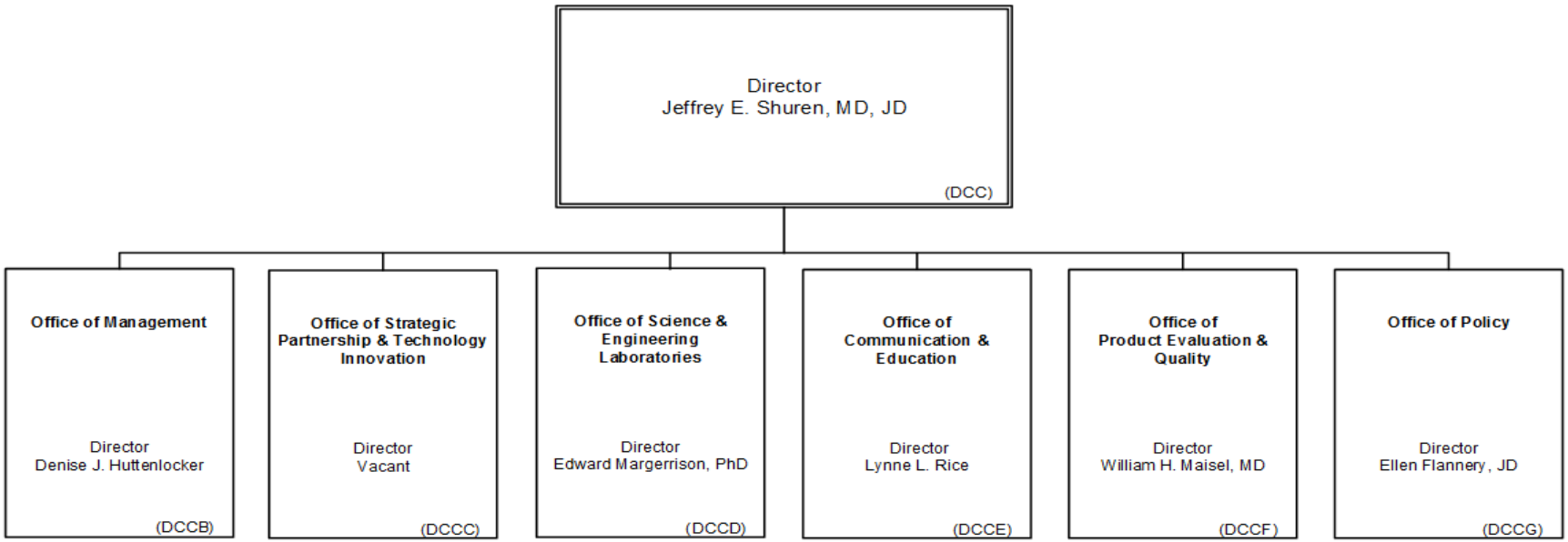
- Food & Drug Acts of 1906
- Federal Food, Drug, and Cosmetic Act (FDCA) of 1938
- The Kefauver-Harris Amendments of 1962 (drug effectiveness)
- Radiation Control for Health and Safety Act of 1968
- Medical Device Amendments of 1976
- 1978: Current Manufacturing Practice (cGMP) Final Rule
- Safe Medical Devices Act (SDMA) of 1990
- 1996: Revamped Quality System (QS) Final Rule
- Food and Drug Administration Modernization Act (FDAMA) of 1997
- Medical Device User Fee and Modernization Act (MDUFMA) of 2002
- FDA Amendments Act (FDAAA) of 2007
- 2013: Unique Device Identifier (UDI) Final Rule
- 21st Century Cures Act of 2016

https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/default.htm

https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/default.htm

October 2019

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health



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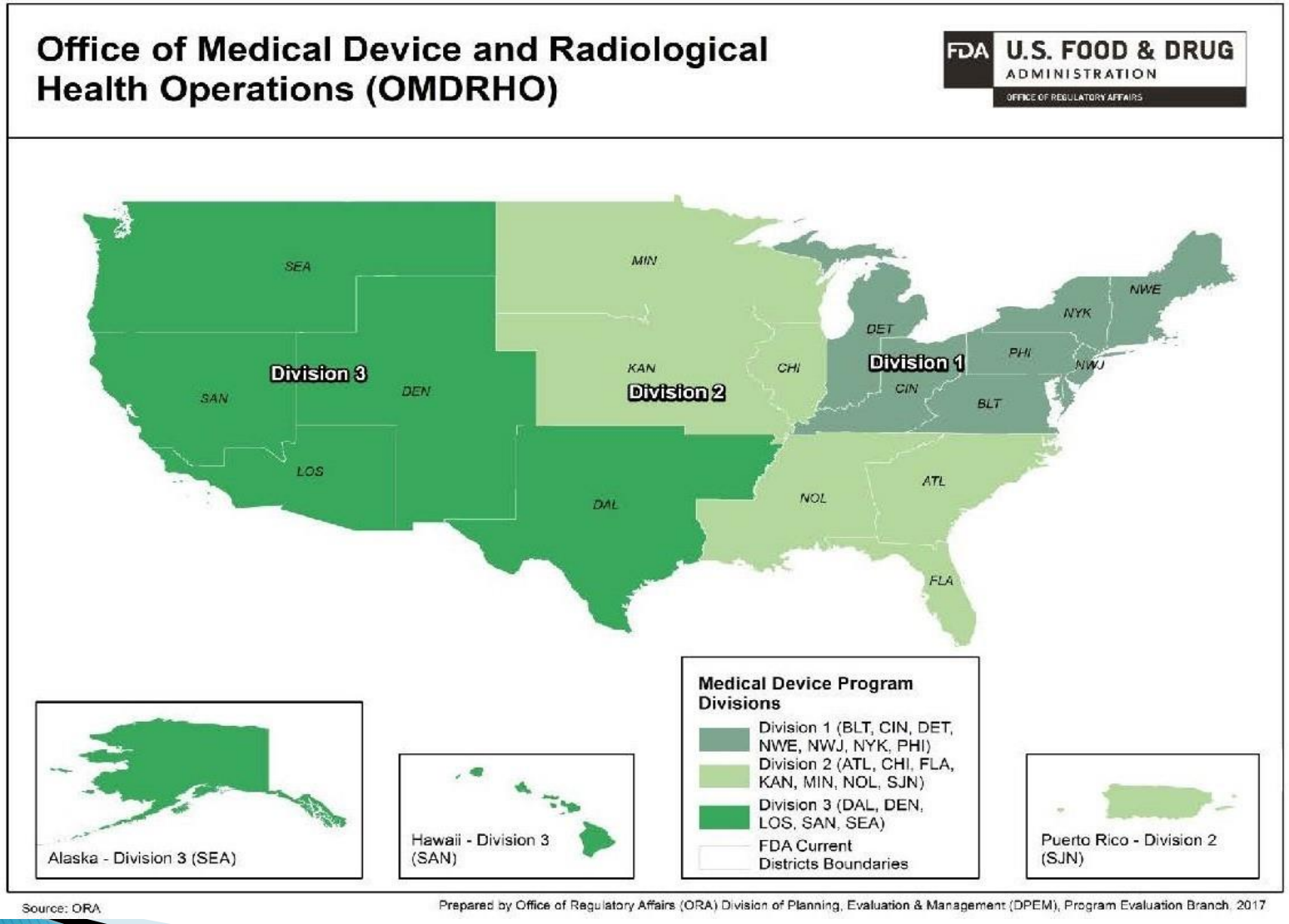
FDA Office of Regulatory Affairs Realignment



Key FDA Abbreviations for Device Regulation

- 510(k) – Pre-Market Notification Submission (510k "Clearance")
- cGMP – Current Good Manufacturing Practice
- IDE – Investigational Device Exemption
- HDE – Humanitarian Device Exemption
- PMA – Pre Market Approval Application (PMA "Approval")
- PDP – Product Development Protocol
- MDR – Medical Device Report
- RE – Reasonable Assurance
- SE – Safety / Efficacy (or Effectiveness)
- QSR – Quality System Regulation (or Requirements)

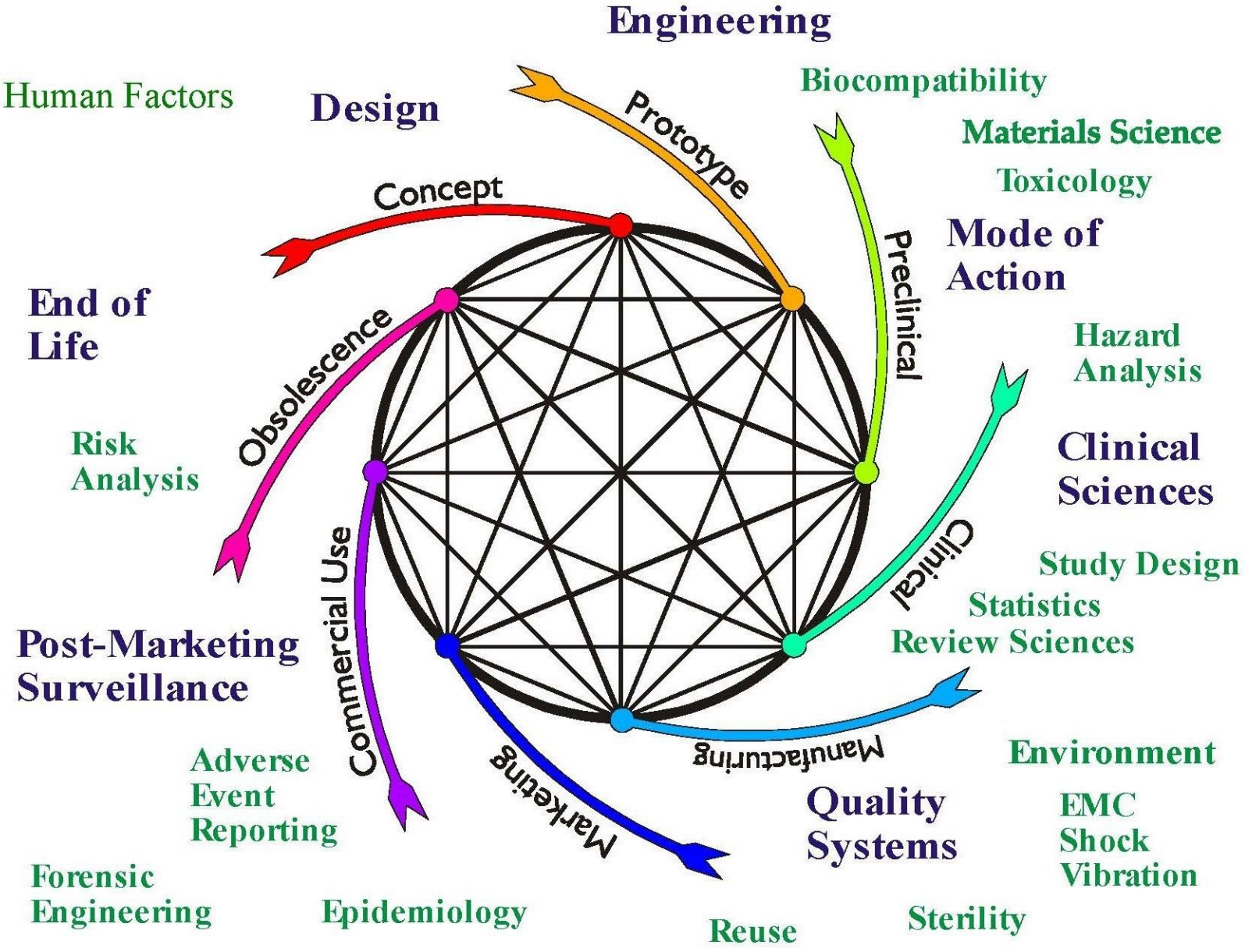
Definition of a Medical Device

an FDA regulated device is an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, 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.
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of 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 any of its primary intended purposes

- Pre-Clinical Evaluation and Development
- Good Laboratory Practices (GLPs)
- Clinical Trials
- Investigational Device Exemption (IDE) requirements
- Institutional Review Boards (IRBs)
- Design Controls
- Quality System Regulation (QSR)
- Manufacturing, Processing, Packaging and Repackaging, Labeling and Relabeling, and Distributing
- Premarket clearance, approval or other authorization or exemption
- Site Registration, Product Listing, Recordkeeping
- Imports
- Exports
- Content of Label and Labeling, including user manuals
- Promotion and Advertising
- Supplements, Amendments, Notice of Modifications
- Complaint Handling
- Medical Device Reports
- Corrections, Removals, Recalls
- Corrective & Preventive Actions
- End of Life/Obsolescence

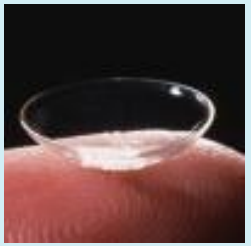
Medical Device Lifecycle



Overview: FDA's 3 Medical Device Classes

Class I
Examination gloves, hand-held surgical instruments
General Controls
Most exempt from premarket submission

Class II
Diagnostic ultrasound, eye contacts
Special Controls
Premarket Notification (510k clearance)



Class III
Joint replacements, heart valves
Premarket Approval (PMA)

Device Classification: Class I

- General controls sufficient to provide reasonable assurance of safety and effectiveness
- General Controls
  - Adulteration and misbranding provisions
  - Establishment registration and device listing
  - Recall notification and repairs
  - Replacement or refund
  - Records and Medical Device Reports (MDR)
  - Good Manufacturing Practices (most are exempt)
  - 510k clearance where required (most are exempt)
- Examples: scalpels; tongue depressors

See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

- Basic authorities that are the framework for FDA's regulation of medical devices

- Apply to all medical devices regardless of classification, unless the type of device is exempted by regulation from specific requirements, e.g., some Class I devices are exempt from 510k, QSR and/or MDR requirements

- **Establishment registration and device listing**
- **Labeling**
- **Misbranding**
- **Adulteration**
- **Quality Systems**
- **Records and Reports & Medical Device Reporting (MDR)**
- **510(k) clearance, unless exempt**

Device Classification: Class II

- General controls alone insufficient to provide reasonable assurance of safety and effectiveness
- Generally must meet general controls
- Most Class II devices require 510(k) **clearance**
- Many are subject to Special Controls, which can include:
  - Performance Standards
  - Post-market surveillance
  - Patient registries and/or guidelines, special labeling
  - "Other Appropriate Actions" as identified by CDRH
- Examples: lasers for general surgery, diagnostic x-ray systems

See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

- General controls alone are insufficient to assure safety and effectiveness of Class II devices
- Existing methods are available to provide such assurances
- Special controls may include special labeling requirements, mandatory performance standards and post-market surveillance
- A few Class II devices are exempt from the premarket notification

- Performance Standards
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)
- Post-market Surveillance Studies
- Patient Registries
- Guidances for 510k's (e.g., Glove Guidance Manual)

Device Classification: Class III

- General controls and special controls alone are insufficient to provide reasonable assurance of safety and effectiveness

- Applicable to a device that is
  - Purported or represented to be for a use in supporting or sustaining human life or
  - For a use which is of substantial importance in preventing impairment of human health; or
  - Presents a potential unreasonable risk of illness or injury; or

  - Is not substantially equivalent to a legally marketed Class I, Class II or pre-amendment (device marketed before May 28, 1976) Class III device for which PMAs have not been called for by FDA

FDCA Section 512, 21 USC 360c

Device Classification: Class III (con't)

- Class 3 devices are the most stringently regulated, and usually are devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury
- Must comply with general controls
- Require premarket **approval** & are subject to conditions of approval
- Examples: replacement heart valves, implantable defibrillators, many joint or spinal replacement devices, lasers to treat certain eye diseases

- Pre-amendment Class III devices - can be submitted and cleared by FDA via a 510(k) until a PMA is called for by FDA

FDA Pathways to Market for Devices: Typical Approaches

Premarket Notification (PMN or 510(k))

- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective – "substantially equivalent" – to a legally marketed device that is not subject to PMA.
- Class I, II, or III (pre-amendment)
- Change or modification to a cleared 510(k) that could significantly affect the safety or effectiveness of a device

Premarket Approval (PMA)

- Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices
- Applicant must demonstrate device's safety and effectiveness, supported by clinical data)
- Class III (new, high risk devices with no predicate device; new high risk indications)
- PMA supplement and change notice requirements apply to approved devices

510(k) – PMA Comparison

- Substantial Equivalence
- Compare to a Predicate Device
- May need Clinical Data or Images
- Small Volume of Information and Data
- 510(k) under FDA Review is Confidential
- 90 day review is goal for over 90% of submissions
- ***Cleared*** by FDA
- Post-Clearance – 510(k) Summary is Made Public

- Safety and Effectiveness
- Scientific Evidence
- Clinical Data
- Large Volume of Information and Data
- Bioresearch Monitoring
- Pre-Approval Inspection
- PMA under FDA Review is Confidential
- ***Approved*** by FDA
- Post-Approval – Summary of Safety and Effectiveness is Made Public

Investigational Device Exemptions (IDEs)

- Regulations at 21 CFR Part 812 allow for shipment/distribution of unapproved medical devices to conduct clinical trials
- Significant risk clinical trials require an IDE submission to FDA
- Non-significant risk studies require IRB review/approval and compliance with applicable provisions of Part 812
- Regulations prohibit:
  - Promotion or test marketing of an investigational device
  - Commercialization of an IDE (cannot charge more than cost recovery)
  - Unduly prolonging investigation
  - Claiming that device is safe or effective for study indication or other unapproved indication
- Section 812.2(c) exempts a few categories of activities (e.g., certain diagnostic tests not used to make clinical decisions, shipment for consumer preference testing that does not put subjects at risk)

Additional Paths to Market and Pre-market Strategies

Product Development Protocol (PDP)

- Alternative to PMA processes
- Combines the IDE and PMA procedures with preclinical processes, See 21 CFR 814.19
- Objective is to obtain early agreement on the data and information necessary to approve the device; once agreement is reached, the sponsor fulfills the obligations of the PDP to submit & obtain approval.

Humanitarian device exemption (HDE)

- Limited to 4,000 patients per year
- First obtain Humanitarian Use Device (HUD) designation, then HDE generally similar to PMA, but data focuses primarily on safety, see 21 CFR 814 Subpart H
- Significant restrictions on sale/marketing

Additional Paths to Market & Pre-market Strategies

Reclassification Petitions

Section 513(g) Requests

- Written requests for information regarding the class in which a device has been or the requirements applicable to a device
- Most often submitted to:
  - Determine whether a product is subject to FDA regulations
  - Determine whether a device is exempt from the 510(k) requirements of the Act
  - Determine whether a 510(k) is needed for a modification to one's device
  - Determine the least burdensome regulatory pathway for a device, which introduces a new technology or a new intended use
- FDA to respond in writing within 60 days with info on classification of the device (if any) and requirements applicable to the device (if it is a device)

https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209851.pdf

Additional Paths to Market and Pre-market Strategies

De Novo Classification

- Established through FDAMA in 1997 as an alternate pathway to classify novel devices of low to moderate risk that had automatically been placed in Class III after receiving a "not substantially equivalent" (NSE) determination in response to a 510(k). With the 2012 FDASIA, sponsors can submit requests for novel low to moderate risk devices without first being required to submit a 510(k).
- Two options for *de novo* classification:
  - Option 1: Any person who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a *de novo* request for the FDA to make a risk-based evaluation for classification of the device into Class I or II.
  - Option 2: Any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may submit a *de novo* request for the FDA to make a risk-based classification of the device into Class I or II, without first submitting a 510(k) and receiving an NSE determination.
- Devices that are classified through the *de novo* process may be marketed and used as predicates for future 510(k) submissions.

https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm232269.htm

Combination Products

- Combination Products Defined in 21 CFR 3.2(e)

  - A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
  - Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
  - A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
  - Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Primary Jurisdiction

- A combination product is assigned to an Agency Center or alternative organizational component that will have primary jurisdiction for its premarket review and regulation.

- Under section 503(g)(1) of the Act, assignment to a center with primary jurisdiction, or a lead center, is based on a determination of the "primary mode of action" (PMOA) of the combination product.

  - If the PMOA of a device-biological combination product is attributable to the biological product, then the Agency component responsible for premarket review of that biological product would have primary jurisdiction for the combination product.

What is a Request for Designation?

- An RFD is also referred to as an applicant's letter of request (see 21 CFR 3.2(j)). It is a written submission to OCP. RFDs generally request a determination of (1) the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and/or (2) either the component of FDA that will regulate the product if it is a non- combination product, or which Agency Center will have primary jurisdiction for premarket review and regulation if it is a combination product.

- A letter of designation, see 21 CFR 3.2(i), (alternatively referred to as a designation letter) is FDA's formal response to an RFD and is a binding determination with respect to classification and/or center assignment that may be changed under conditions specified in Section 563 of the FD&C Act and 21 CFR 3.9 in the regulations.

Remember … the "R" in CDRH is its own regulatory framework

- "Electronic product radiation" means – (A) any ionizing or non-ionizing electromagnetic or particulate radiation, or (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product. See FDCA Sections 531-542, 21 USC 360hh - 360ss.
- Examples of electronic products:
  - Medical: diagnostic x-ray or ultrasound imaging devices, microwave or ultrasound diathermy devices, microwave blood warmers or sterilizers, laser coagulators, ultrasound phacoemulsifiers, x-ray or electron accelerators, sunlamps, ultraviolet dental curing devices;
  - Non-medical: microwave ovens, televisions receivers and monitors (video displays), entertainment lasers, industrial x-ray systems, cordless and cellular telephones, industrial RF sealers of plastics and laminates, laser CD players.
- If a medical device and an electronic product, product generally needs to comply with both all applicable medical device regulations and all applicable electronic product regulations

21 CFR Subchapter J Parts 1000-1050.

21st Century Cures Act

FDA Draft guidance with interpretations of several of the medical software provisions in the 21st Century Cures Act, explaining their effect on pre-existing FDA policy, including policy on:

- Mobile medical applications;
- Medical device data systems, used for the electronic transfer, storage, display, or conversion of medical device data;
- Medical image storage devices, used to store or retrieve medical images electronically;
- Medical image communications devices, used to transfer medical image data electronically between medical devices;
- Low-risk general wellness products; and
- Laboratory workflow

FDA's Digital Health Innovation Action Plan

From mobile medical apps and fitness trackers, to software that supports the clinical decisions doctors make every day, digital technology has been driving a revolution in health care.

FDA's Digital Health Innovation Action Plan outlines FDA's efforts to reimagine FDA's approach for assuring timely access to high-quality, safe and effective digital health products.

This plan includes:

- Guidance on the medical software provisions of the 21st Century Cures legislation;
- Launching an innovative pilot precertification program to develop a new approach to digital health technology oversight (FDA Pre-Cert for Software); and
- Building FDA's bench strength and expertise in CDRH's digital health unit

Software Precertification (Pre-Cert) Program

The goals of this Software Precertification (Pre-Cert) Program are to:

- enable a modern and tailored approach that allows software iterations and changes to occur in a timely fashion;
- ensure high quality medical product software throughout the life of the product by enabling companies to demonstrate their embedded culture of quality and organization excellence (CQOE); and
- be a program that learns and adapts and can adjust key elements and measure based on the effectiveness of the program

What does it Mean to be Pre-certified

The goal of FDA's new approach is for the FDA to, after reviewing systems for software design, validation and maintenance, determine whether the company has a culture of quality and organizational excellence.

Because the precertification process would give the FDA assurance that the organization produces high quality, safe, and effective products, precertified companies could submit less information to us than is currently required before marketing a new digital health tool.

In some cases, pre-certified companies could not submit a premarket submission at all. In those cases, the precertified company could launch a new product and immediately begin post-market data collection. The post-market data could help the FDA assure that the new product remains safe and effective as well as support new uses.

Precertification is a concept; through this pilot the FDA and participants will have a better sense of what organizational excellence means and how organizations can become "excellent."

International Medical Device Regulators Forum approach to clinically evaluating Software as a Medical Device

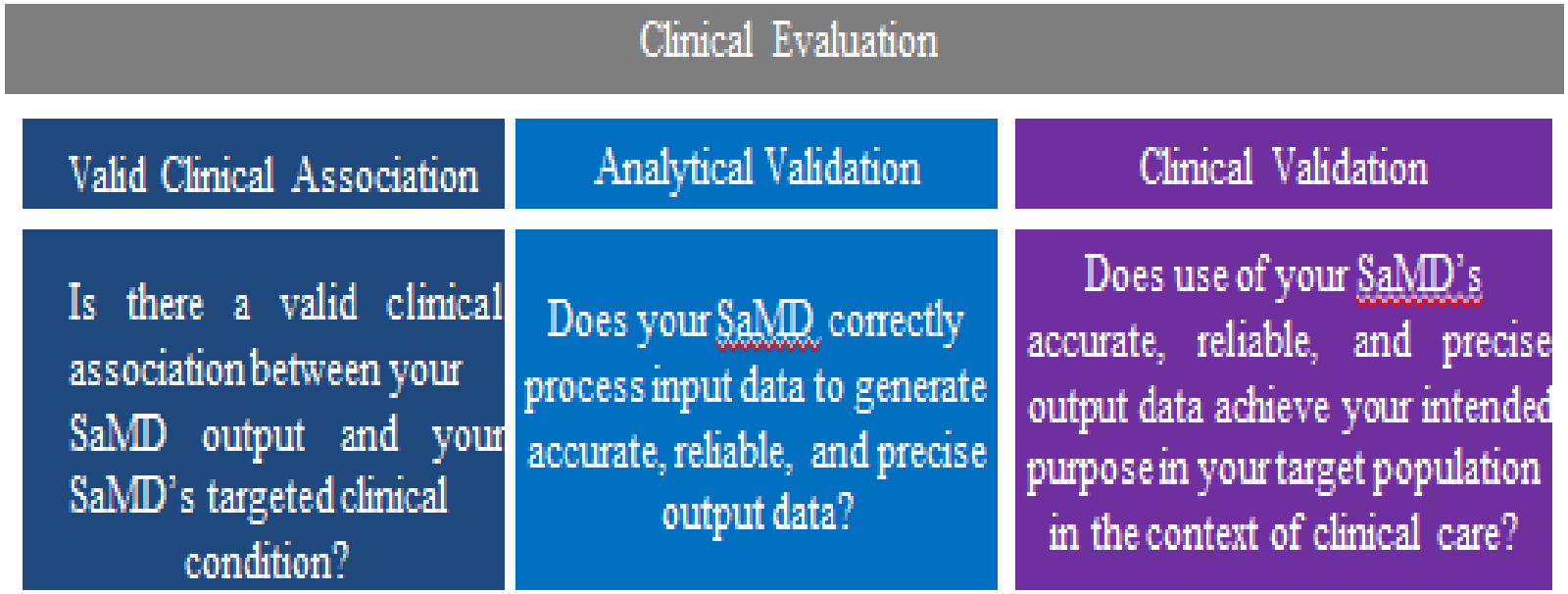


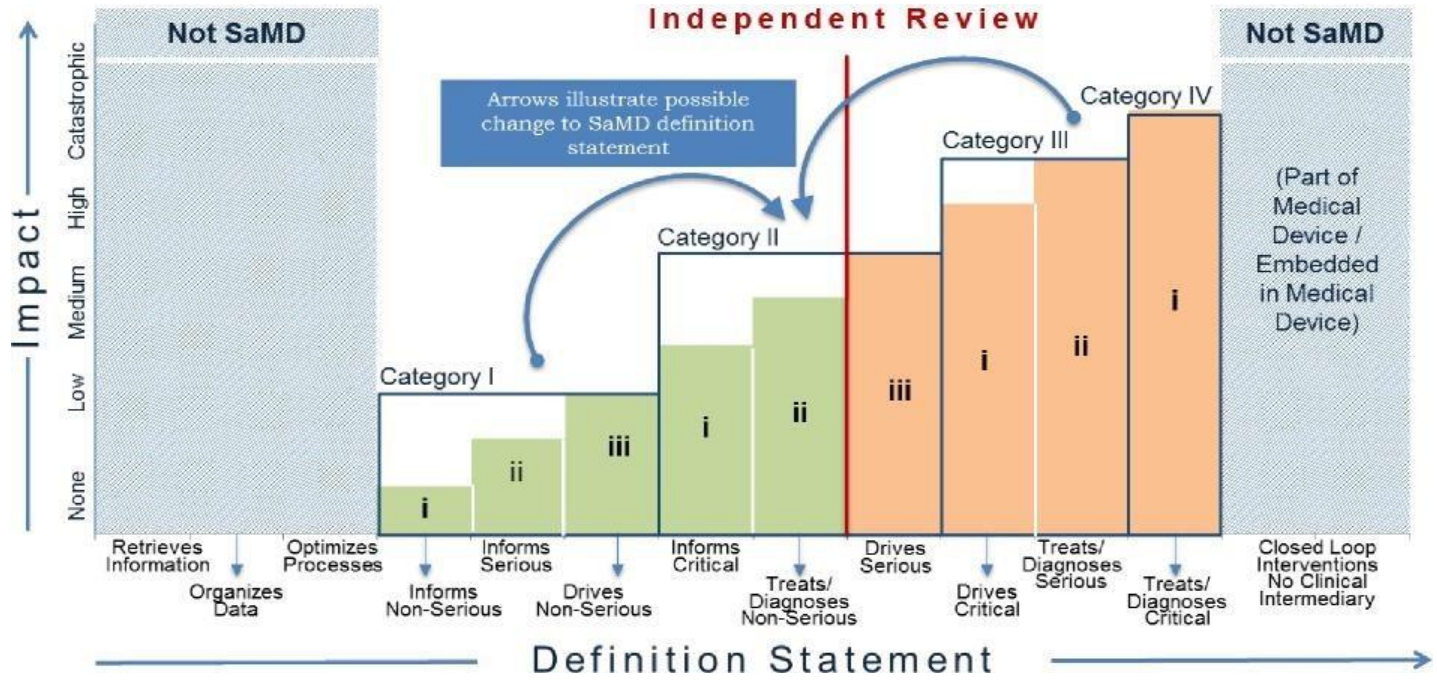
Figure 1 - Clinical Evaluation Process

International Medical Device Regulators Forum Categories of Software

The four categories (I, II, III, IV) are based on the levels of impact on the patient or public health where accurate information provided by the software to treat or diagnose, drive or inform clinical management is vital to avoid death, long-term disability or other serious deterioration of health, mitigating public health.

The categories are in relative significance to each other. Category IV has the highest level of impact, Category I the lowest.

Independent Review of Software's Clinical Evaluation



Post-Market Surveillance

Monitoring medical device performance after a device is approved or cleared for marketing to identify problems and safety issues that occur during widespread clinical and home use.

Detect and evaluate problems early

Address those problems that may emerge with real-life use

FDA's Postmarket Surveillance System: MedWatch

FDA's nationwide adverse event reporting system

Relies on reports of problems by the user and manufacturer

Manufacturers, Consumers and User Facilities (such as hospitals) report under MedWatch

Adverse Events

An event whereby a medical device has, or may have, caused or contributed to a death or serious injury.

Includes events resulting from:

- Device failure
- Device malfunction
- Improper or inadequate device design
- Manufacturing problems
- Labeling problems
- Training issues
- Use error

Telemedicine Devices – New Risks

Environment

- Children
- EMI
- Location
- Noise
- Pets and vermin
- Power outages and sources
- Public emergencies
- Safety
- Sanitation
- Space
- Temperature, air quality, humidity
- Water

Use

- Compatibility with lifestyle and usefulness
- Instructions for use are poor or nonexistent for lay users
- Interface and ease of use
- Off label use
- Ruggedness of the device for many conditions
- Selling Rx devices on the Internet
- User's educational level
- User's emotional stability
- User's physical capabilities

What Types of Issues Should You Look Out For in Software Devices?

- Defects
- Software problems
- Hacking/Virus Infections
- Failure to work as intended/malfunction
- Instructions/labeling/packaging issues
- Interactions/interference with other devices, or other electronic equipment in the home
- Use errors
- Human Factors issues
- Combinations of the above

Digital Pills

- Digital pills are the ingestible micro sized sensors, associated to a small wearable skin sensor patch that conveys the composed data to the linked digital device such as mobiles, smart phones.
- Data collected from these pills enables the patients to share the data with their doctors or physicians.
- The technology aim is to provide healthcare professionals with a tracking system (GPS) of sorts for the human body so that they can chase patient's compliance with their routine.
- Better tailor or customize medicine as per the patient’s requirement.
- Expected to solve problems faced by pharmaceutical companies and insurers, which includes lower drug sales due to missed doses and higher medical costs handling patients whose conditions worsen.

FDA 510(k) Clearances for Telehealth Devices

- Pear Therapeutics' reSET system for the treatment of substance abuse
- Abbott Diabetes Care's Freestyle Libre Flash Glucose Monitoring System
- DarioHealth Corp., glucose meter and cleared companion app that syncs with the glucose meter and includes a nutrition guide, logbook, and monitoring system
- Cochlear Limited- Nucleus 7 Sound Processor, the first cochlear implant sound solution
- Dictum Health, telehealth platform, virtual exam room -spirometry Sp02, blood pressure, height and weight, temperature, and ECG
- Osprey Medical's DyeVert system —uses a Bluetooth equipped smart syringe and an associated monitor to track exactly how much dye is being used
- Milestone Scientific - technology that will be used for epidural procedures, and allows anesthesiologists and other clinicians the ability to determine the pressure at the tip of a needle in real-time.
- Medtronics Intellis system, a new implantable pain management device that can be programmed wirelessly via a Samsung tablet.
- Adherium, inhaler monitoring device for AstraZeneca's Symbicort
- Viz.AI's clinical decision support tool app Contact uses artificial intelligence (AI) to analyze CT images for signs of stroke

Enforcement Actions Under the Federal Food, Drug and Cosmetic Act

- Prohibited Acts – Generally some type of activity performed with an adulterated or misbranded product or resulting in an adulterated or misbranded product
- Remedies:
  - Seizure
  - Injunction
  - Civil Money Penalties
  - Civil and Criminal Penalties (strict liability)

- Other remedies include Warning Letters, untitled letters, Consent Decreesand other administrative penalties
- Note that enforcement actions by the FDA may establish important policies

Engaging the FDA

- Participation in the Notice and Comment Rulemaking Process
- Pre-Submission Meetings and Other Formal and Informal Meetings
- Contacting the Ombudsman
- Citizen Petitions

Understand the Current Climate at FDA

- Periodically significant safety issues surface with a number of drugs and medical devices
- There has been challenges to the fundamental integrity and the ability of the drug /medical device approval/clearance process to safeguard the public health
  - **Increased Congressional scrutiny**
  - **Public awareness and criticism**
- FDA's response:
  - **More conservative decision making**
  - **Greater scrutiny of the data**
  - **Seeking consensus review**
  - **Increased focus on FDA field inspections**
  - **User fee time pressure for completing reviews**

Understand the Current Climate at FDA

- Recommendation
  - Understand FDA's expectations
  - Try to address requirements in FDA Guidance, communicated in meetings and approvals of similar products
  - Seek information and guidance from FDA and outside experts
  - Companies often understand their products more thoroughly than FDA
    - Educate
    - Hear FDA's concerns
    - Attempt to respond
- Remember – FDA does not get it right every time
  - Can responsibly challenge FDA decision making
  - Need good science and legal / regulatory precedents


Grin & Bear It
By Fred Wagner
HIRACLE DRUG CO.
IF IT WORKS IT'S A HIRACLE
HIRACLE DRUG CO.
"We got a 'Nice try' from the FDA."

Thank You and Questions

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