Is My Digital Health Product a Medical Device Regulated by FDA?

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FDLI's *Fundamentals of Digital Health Regulation: Successfully Navigating Your Product Through FDA*

Johnson&Johnson

Global Legal Organization

1 Overview of FDA

2 Device Definition

- Federal Food, Drug, and Cosmetic Act (FDCA) definition; intended use, and FDA's risk-based regulatory approach
- Regulation of software; exclusions from the definition of device under the FDCA, and FDA digital health guidance

3 Agency Enforcement Discretion

- What is enforcement discretion?
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- Prohibited acts and enforcement options
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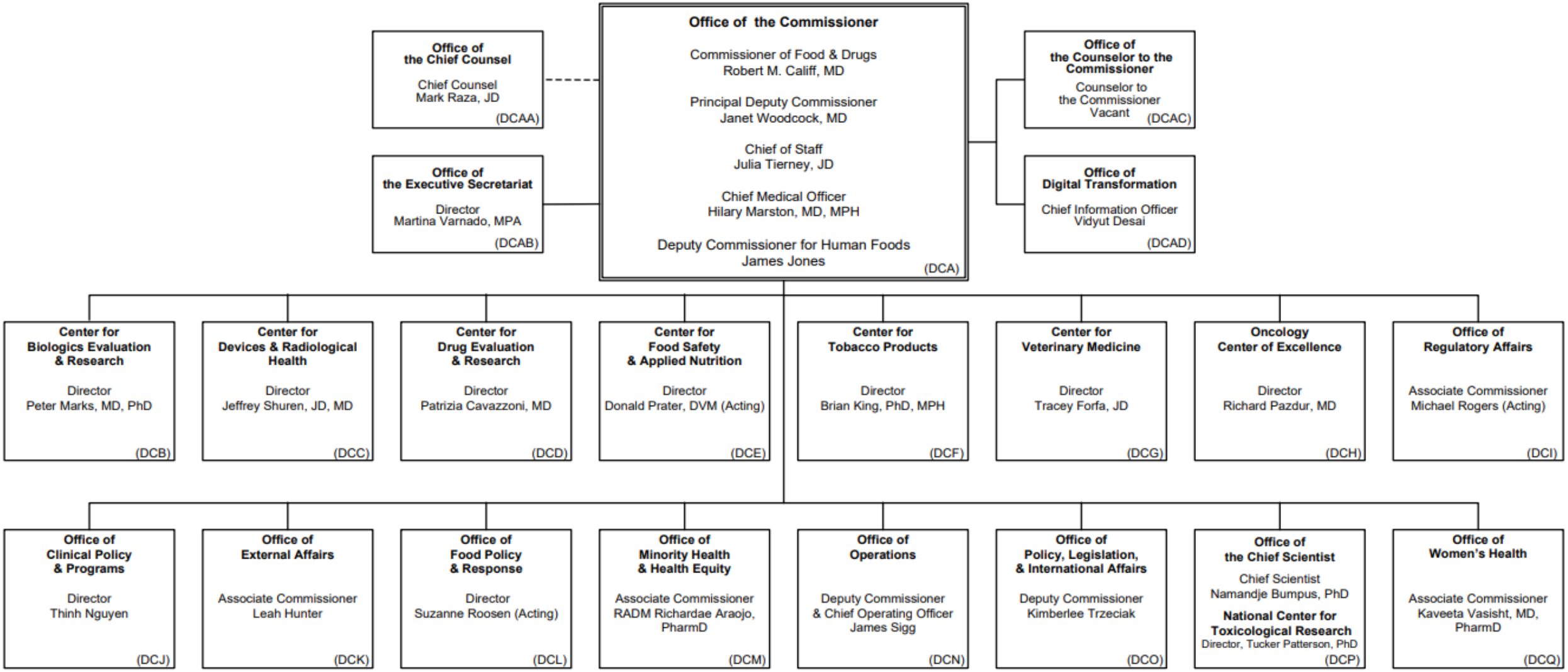
Overview of FDA

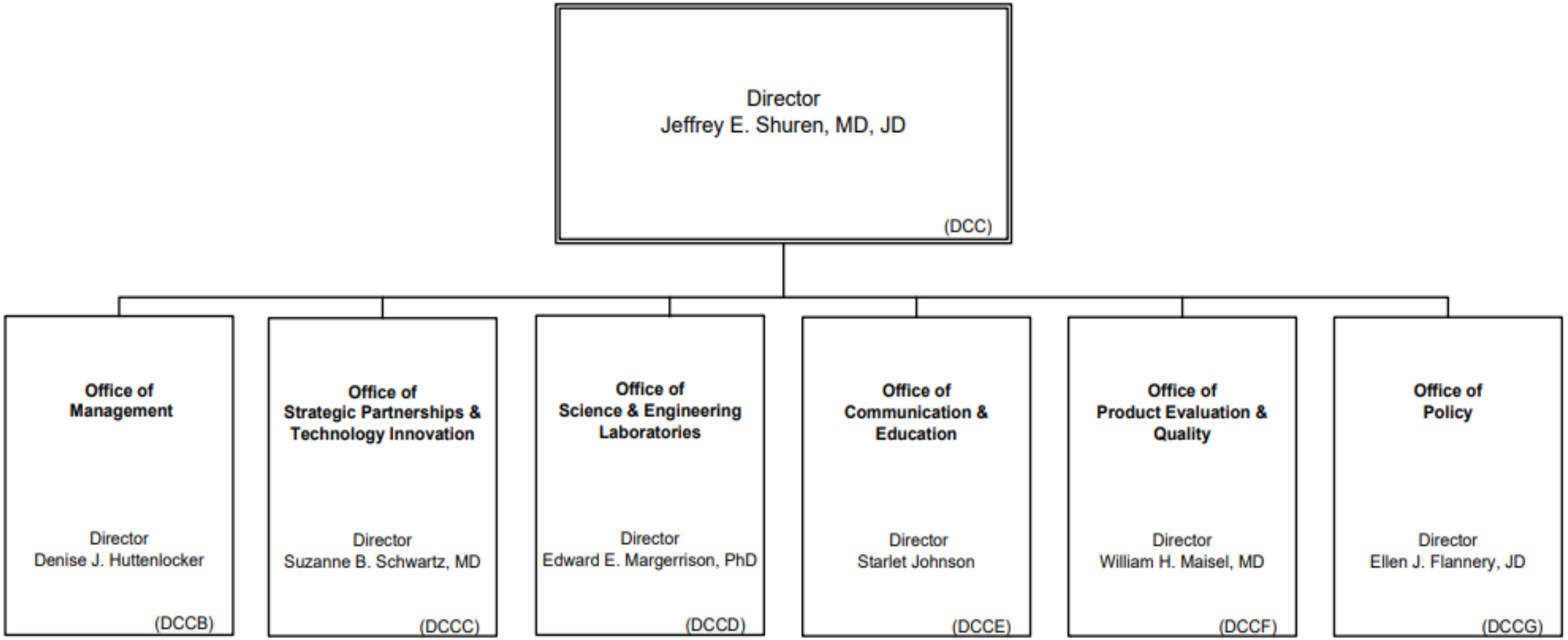
Org Chart: FDA



Legend:
--- Direct report to DHHS General Counsel

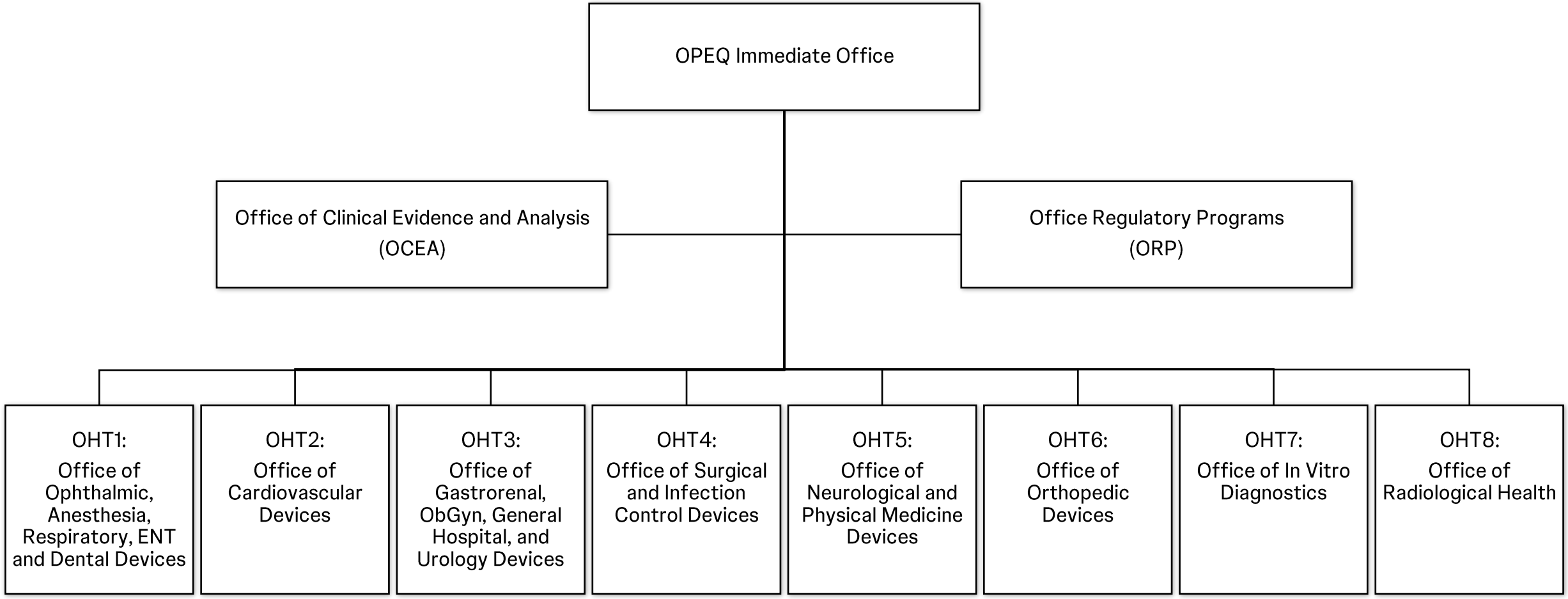
Source: https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart

Org Chart: CDRH



Source: https://www.fda.gov/about-fda/fda-organization-charts/center-devices-and-radiological-health-organization-chart

Org Chart: OPEQ



Source: https://www.fda.gov/about-fda/cdrh-offices/office-product-evaluation-and-quality

Device Definition

Federal Food, Drug, and Cosmetic Act

- The FDCA provides FDA authority to oversee and regulate:
  - Foods
  - Drugs
  - Cosmetics
  - Medical devices
  - Biologics
  - Radiation-emitting products
  - Veterinary products
  - Tobacco products
- Passed in 1938
  - Amended in 1976 to establish medical device framework

FDR signing the FDCA on June 25, 1938

Source: https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act

Definition of a Medical Device

FDCA Section 201(h)

Medical Device

Defined as 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 its primary purpose as a drug (e.g., no chemical action or metabolism)

AND

Which is **not** a software function excluded from the device definition by section 520(o) of the FDCA

Intended Use

21 CFR § 801.4

Intended use is a key component of the device definition

Intended Use

Intended use refers to the general purpose of a product

- Determined by objective intent
- May be shown by expressions, the design or composition of a product, or by the circumstances surrounding the distribution of a product

Intended use can significantly affect how, and even whether, a product is regulated as a device

Example

Intended Use A	Intended Use B
Maintaining good health	Cardiac rehabilitation of heart surgery patients
Not a Device	Device

FDA's Risk Based Regulatory Approach

Devices are classified and regulated based on the risk that they pose

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption
I				
II				
III				

FDA's Risk Based Regulatory Approach (cont'd)

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption
I	Lowest	• Minimal potential for harm		
II	Moderate	• Higher risk than class I		
III	Highest	• Sustain or support life • Implanted • Potential or unreasonable risk of illness or injury		

FDA's Risk Based Regulatory Approach (cont'd)

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption
I	Lowest	• Minimal potential for harm		
II	Moderate	• Higher risk than class I		
III	Highest	• Sustain or support life • Implanted • Potential or unreasonable risk of illness or injury		

FDA's Risk Based Regulatory Approach (cont'd)

Regulatory controls describe the appropriate level of regulatory oversight necessary to provide reasonable assurance of a device's safety and effectiveness

General Controls

- Adulteration
- Misbranding
- Establishment registration
- Device listing
- Medical device reporting
- Good manufacturing practices

See also: sections 501, 502, 510, 516, 518, 519, and 520 of the FDCA

Special Controls

Can include:

- Performance standards
- Testing
- Postmarket surveillance
- Patient registries
- Special labeling requirements

Found in classification regulation for device type

Premarket Approval

Scientific review process to ensure safety and effectiveness

Most stringent/rigorous review

FDA's Risk Based Regulatory Approach (cont'd)

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption
I	Lowest	• Minimal potential for harm	• General	
II	Moderate	• Higher risk than class I	• General • Special	
III	Highest	• Sustain or support life • Implanted • Potential or unreasonable risk of illness or injury	• General • PMA	

FDA's Risk Based Regulatory Approach (cont'd)

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption
I	Lowest	• Minimal potential for harm	• General	• 510(k) • 510(k) Exempt *(Most are 510(k) Exempt)*
II	Moderate	• Higher risk than class I	• General • Special	• 510(k) • 510(k) Exempt
III	Highest	• Sustain or support life • Implanted • Potential or unreasonable risk of illness or injury	• General • PMA	• PMA

Software as a Medical Device

Defining "digital health" for medical devices

Software as a Medical Device (SaMD)
"Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device"

- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device

- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software

Source: International Medical Device Regulators Forum (IMDRF) SaMD Working Group Final Document: "Software as a Medical Device (SaMD): Key Definitions" (9 December 2013)

FDA Digital Health Guidance

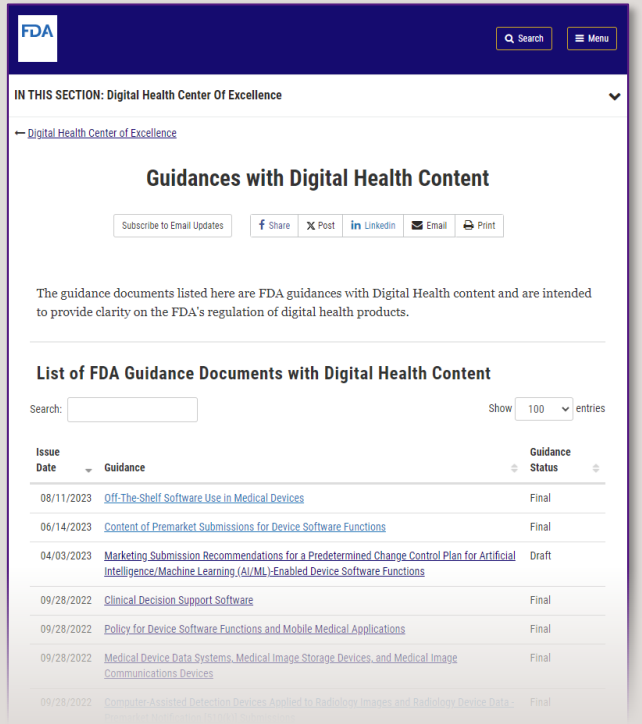
CDRH's Digital Health Center of Excellence (DHCoE) is a useful resource for navigating the digital health regulation environment

Digital Health Center of Excellence

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

Guidances with Digital Health Content

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

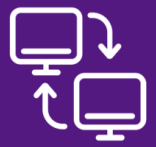


Digital Health Policy Navigator

https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator

SaMD Exclusions

The 21st Century Cures Act (enacted December 2016) amended the definition of "device" in the FDCA to exclude certain software functions

	Excluded Software Functions
 Administrative Software	Administrative support of a health care facility
 General Wellness	Maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
 EPRs	Certain electronic patient records
 MDDS	Transfer, store, convert formats, or display device data, results, and findings and that do not interpret or analyze such data and results (Medical Device Data Systems)
 CDS	Clinical Decision Support functionality

Administrative Support of a Health Care Facility

Examples of Non-Device Software Functions

Processing and Maintenance of Claims Information

Appointment Scheduling

Business Analytics

Determinations of Health Benefit Eligibility

General Wellness

FDCA Section 520(o)(1)(B)

FDCA

Software function is <u>not</u> a device if the product is:

- Intended for maintaining or encouraging a healthy lifestyle

AND

- Unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition

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"General Wellness: Policy for Low Risk Devices" 2019 Guidance

Enforcement discretion for *software and hardware* if the product:

- Is intended only for "general wellness" use, as defined in the guidance
  - This includes certain intended uses that refer to certain chronic diseases and conditions

AND

- Presents a very low risk to users' safety

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

General Wellness Examples

Example A

Software product that tracks and records your sleep, work and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety

Not a Device

Example B

Product that promotes making healthy lifestyle choices such as getting enough sleep, eating a balanced diet, and maintaining a healthy weight, which may help living well with type 2 diabetes

Not a Device

Example C

Software product that is intended to diagnose or treat autism

Device

Example D

Neurostimulation product that claims to improve memory, due to the risks to a user's safety from electrical stimulation

Device

Electronic Patient Records

FDCA Section 520(o)(1)(C)

Electronic patient records are <u>not</u> a device to the extent that such records are the <u>equivalent of a paper medical chart</u>, so long as the records:

Were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals

Are part of health information technology that is certified by the Office of the National Coordinator for Health Information Technology

Are <u>not</u> 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

Medical Device Data Systems

FDCA Section 520(o)(1)(D)

MDDS software is not a device if it:

1. Is solely intended to transfer, store, convert formats, or display clinical laboratory test or other device data, results, and findings, and
2. Does not interpret or analyze such data and results

Both conditions must be met

Medical Device Data

Medical Images

Waveforms

Signals

Other Clinical Data

MDDS (cont'd)

Additional considerations for exclusion from the device definition

2022 Guidance: "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices"

Non-Device MDDS:

- Does not modify the data
- Does not control the functions or parameters of any connected medical device
- Does not analyze or interpret data
- Does not provide active patient monitoring
  - No alarms/alerts/prioritization of patient-related information on multi-patient displays, when clinical context or condition requires a timely response
  - FDA says that this involves analysis/interpretation, and therefore is device functionality

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices

MDDS Examples

Example A

Software that converts digital data generated by a pulse oximeter into a digital format that can be printed

Not a Device

Example B

Application that facilitates the remote display of information from a blood glucose meter, where the user of the meter can independently review their glucose and glucose levels, and which is not intended to be used for taking immediate clinical action

Not a Device

Example C

Application that analyzes radiology images to provide a diagnostic output

Device

Example D

Software that is intended to prioritize patients in an Intensive Care Unit based on their clinical status

Device

Clinical Decision Support

FDCA Section 520(o)(1)(E)

A CDS software function is **excluded** from the device definition if it meets **all** the following criteria:

1. Not intended to acquire, process, or analyze medical image, signals, or patterns
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information
3. Intended for the purpose of supporting or providing recommendations to an HCP
4. Intended for the purpose of enabling an HCP to independently review the basis for such recommendations without the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

"Clinical Decision Support Software" guidance finalized September 2022

- Includes controversial changes narrowing the scope of CDS

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

CDS Criterion 1

Not intended to acquire, process, or analyze medical images, signals, or patterns

Medical Images

- Includes those generated by used of medical imaging systems (CT, x-ray, ultrasound, MRI) and those acquired for a medical purpose (pathology, dermatology)
- Also includes images that weren't originally acquired for a medical purpose but are now being processed or analyzed for a medical purpose

Patterns and Signals

- Signals typically require use of either an IVD or a signal acquisition system
- Pattern is "multiple, sequential or repeated measurements" (ECG waveform, genetic sequences, repeated glucose measurements captured over time)

Examples

✗ Software to enhance, manipulate, measure, identify normal/abnormal structures, determine shape/size/location of suspected nodules in images

✗ Software that analyzes ECG waveforms to detect heart arrythmias

✓ Criterion Met ✗ Criterion Not Met

CDS Criterion 2

Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information

Patient Medical Information

- The type of information that normally is communicated between HCPs in a clinical conversation, or between HCPs and patients in the context of a clinical decision

Other Medical Information

- Peer-reviewed clinical studies, clinical practice guideline
- Information must be independently verified and validated as accurate, reliable, supported by evidence

Examples

✓ Software that analyzes reports from a radiology study

✓ Software that displays an ECG report annotated by an HCP with a description of an abnormal heart rhythm

✓ Criterion Met ✗ Criterion Not Met

CDS Criterion 3

FDCA Section 520(o)(1)(E)(ii)

Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition

A software function meets Criterion 3 if it:

- Provides condition-, disease-, and/or patient-specific recommendations to an HCP to enhance, inform and/or influence a health care decision
- Is **not** intended to replace or direct the HCP's judgment
- Does **not** provide a single, specific, selected output or directive
  - Level of software automation is relevant
  - FDA explicitly is concerned about automation bias
- Is **not** intended to support time-critical decision-making
  - Similar concerns about automation bias

CDS Criterion 3 Examples

Examples

- ✓ Software that provides a prioritized list of preventative, diagnostic, or treatment options
- ✓ Software that provides a list of follow-up or next-step options for consideration
- ✓ Software that provides clinical guidances matched to patient-specific medical information
- ✗ Software that provides time-critical alarms or alerts intended to trigger potential clinical intervention to assure patient safety
- ✗ Software that provides a treatment plan for a specific patient's disease or conditions
- ✗ Software that provides risk probabilities or risk scores (e.g., identifies patients that “may exhibit signs of”)

✓ Criterion Met ✗ Criterion Not Met

CDS Criterion 4

Intended for the purpose of enabling an HCP to independently review the basis for such recommendations without the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Software must enable independent review of the basis for its recommendations so that HCPs rely on their own judgment to make clinical decisions for individual patients

- Time-criticality a factor here as well (FDA says HCPs need sufficient time for independent review)
- This criterion is generally addressed by **labeling considerations** – providing plain language information on:
  - Purpose or intended use of the product
  - Input(s)
  - Algorithm development and validation (including logic or methods, datasets relied upon, clinical study results)
  - Other knowns/unknowns for consideration

Agency Enforcement Discretion

Enforcement Discretion

"...FDA does not intend to object..."

FDA's Enforcement Discretion

FDA has the power to elect to not enforce certain regulatory requirements for devices within its purview, especially in cases where the risk has been deemed low by the Agency

Enforcement discretion is typically reserved for devices that have an existing product code, as those devices are generally already well-understood by FDA

Good Guidance Practices

21 CFR § 10.115

GGPs are FDA's policies and procedures for developing, issuing, and using guidance documents

Level 1 Guidances

- Set forth the agency's initial interpretations of new significant regulatory requirements
- Describe substantial changes in FDA's earlier interpretation or policy
- Deal with complex scientific or highly controversial issues

Generally, Level 1 Guidances follow a process of issuance of a draft version for public comment prior to finalization – unless "public participation is not feasible or appropriate"

Level 2 Guidances

- Address existing practices or minor changes in FDA's interpretation or policy
- Typically issued for immediate implementation

Notably, on January 3, 2024, FDA published a notice in the Federal Register asking for input on whether more Level 1 guidances are appropriate for release under the "immediate implementation" provision without prior public comment

Enforcement & Compliance

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Prohibited Acts; Enforcement Options

Specific prohibited acts include (but are not limited to):

- The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded device
- The adulteration or misbranding of any device in interstate commerce
- Failure to submit a 510(k) before marketing a device when one is needed

Enforcement actions by FDA come in many forms, including:

- Untitled Letters
- Warning Letters
- Injunctions / Consent Decrees
- Seizures
- Criminal Prosecutions and Penalties
- Civil Money Penalties
- Administrative Sanctions
- Recalls

FDA Inspections

FDA has authority to conduct inspections at reasonable times, within reasonable limits, and in a reasonable manner. For devices, this includes:

- **Routine** inspections
- **For-cause** inspections
- Compliance **follow-up** inspections
- For **PMAs**: preapproval and postmarket inspections
- For **De Novo requests**: inspections when data integrity and quality concerns arise as during review, or if there are critical or novel manufacturing processes that may affect the safety/effectiveness of the product

Additional FDA Digital Health Considerations

Cybersecurity

AI / ML

Interoperability

AR / VR

... and more!

Thank you!

If you have more questions, please contact:

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