U.S. FOOD & DRUG ADMINISTRATION

Center for Device and Radiological Health

FDA Review of Gynecological and Surgical Devices

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June 13, 2024

Outline

- Authorities and Organization
- Total Product Lifecycle (TPLC) Review of Medical Devices
  - Premarket
  - Postmarket
  - Compliance
- Questions

History of Food, Drug, and Device Laws

- 1938: Food, Drug, and Cosmetic Act
- 1976: Medical Device Amendments
- 1997: Food and Drug Administration Modernization Act
- 2002: Medical Device User Fee and Modernization Act
- 2012: Food and Drug Administration Safety and Innovation Act
- 2016: 21st Century Cures

Device classifications and regulatory requirements also outlined in Title 21 of the Code of Federal Regulations (CFR)

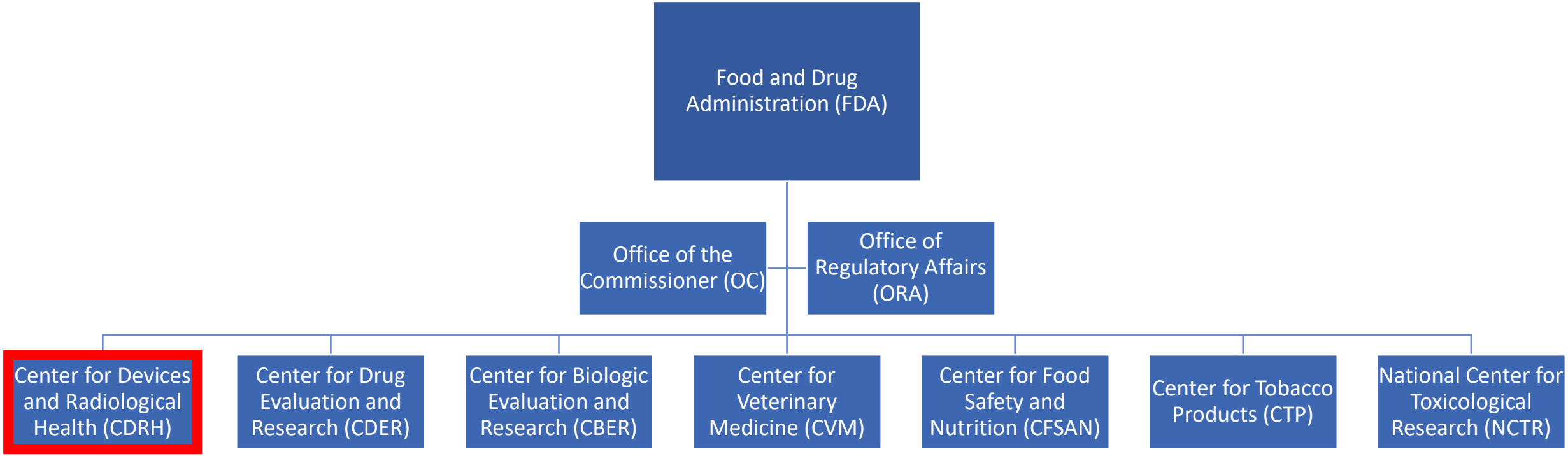
A History of Medical Device Regulation & Oversight in the United States

Laws Enforced by FDA

Milestones in U.S. Food and Drug Law

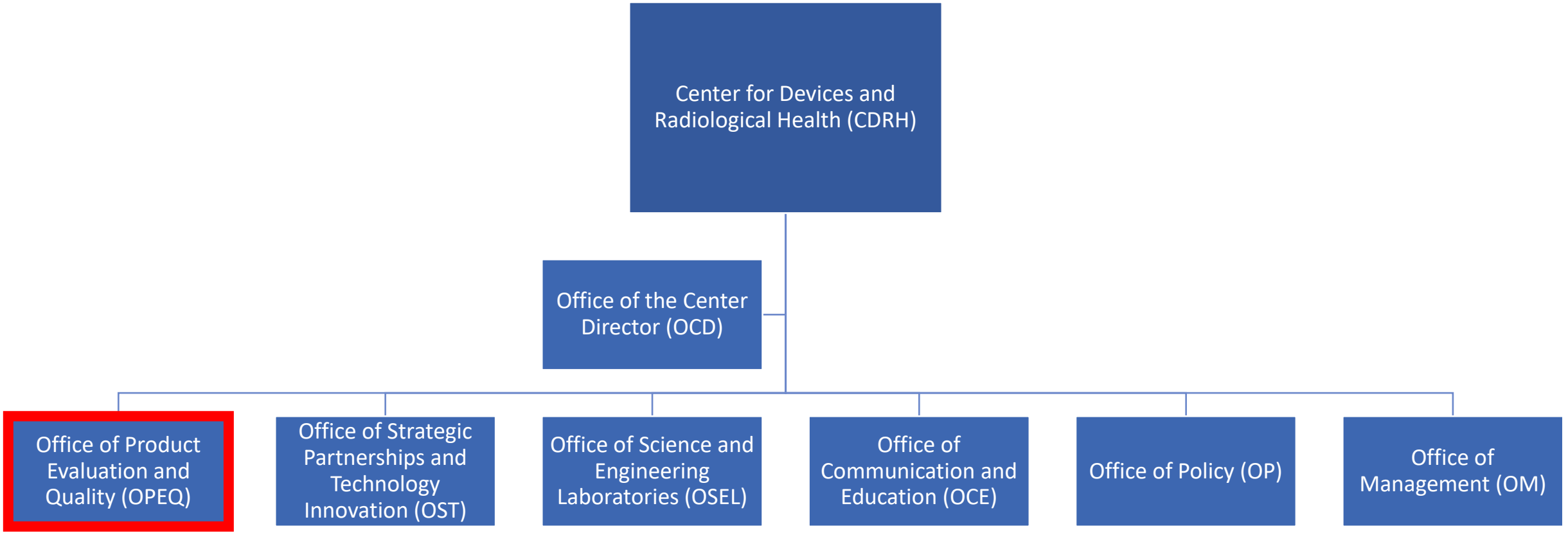
21st Century Cures Act

FDA Organization



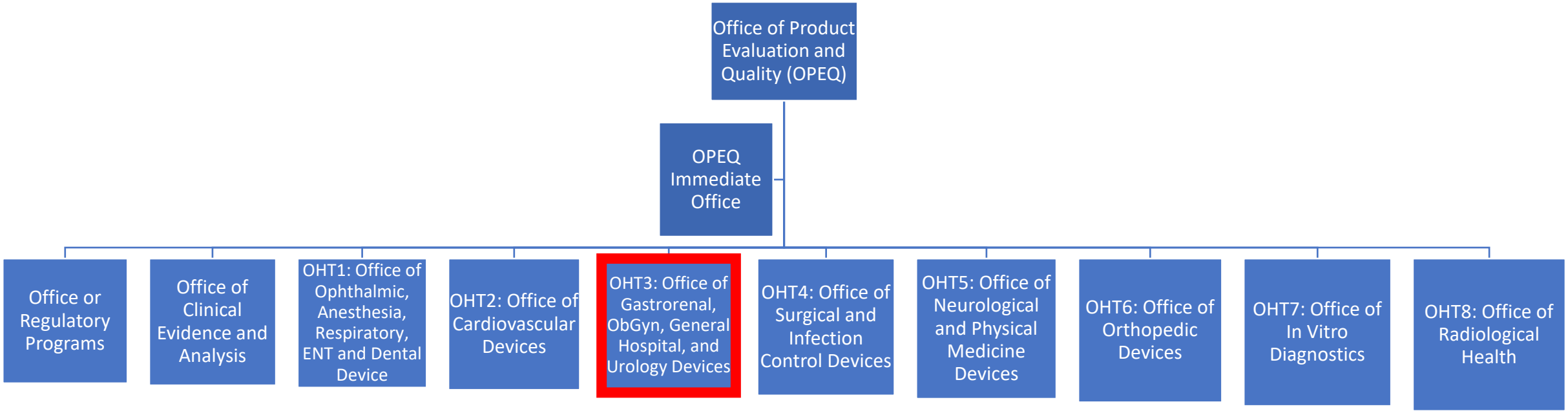
FDA Overview Organization Chart

CDRH Organization



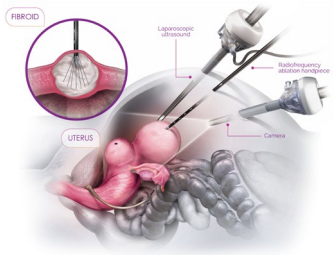
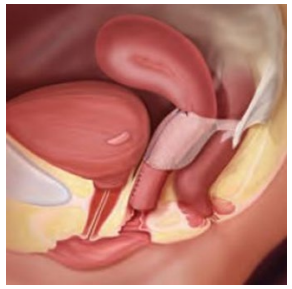
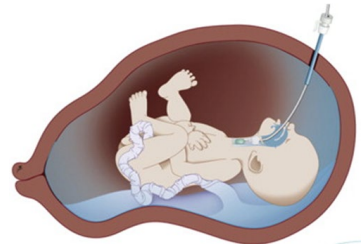
CDRH Management Directory by Organization

OPEQ Organization

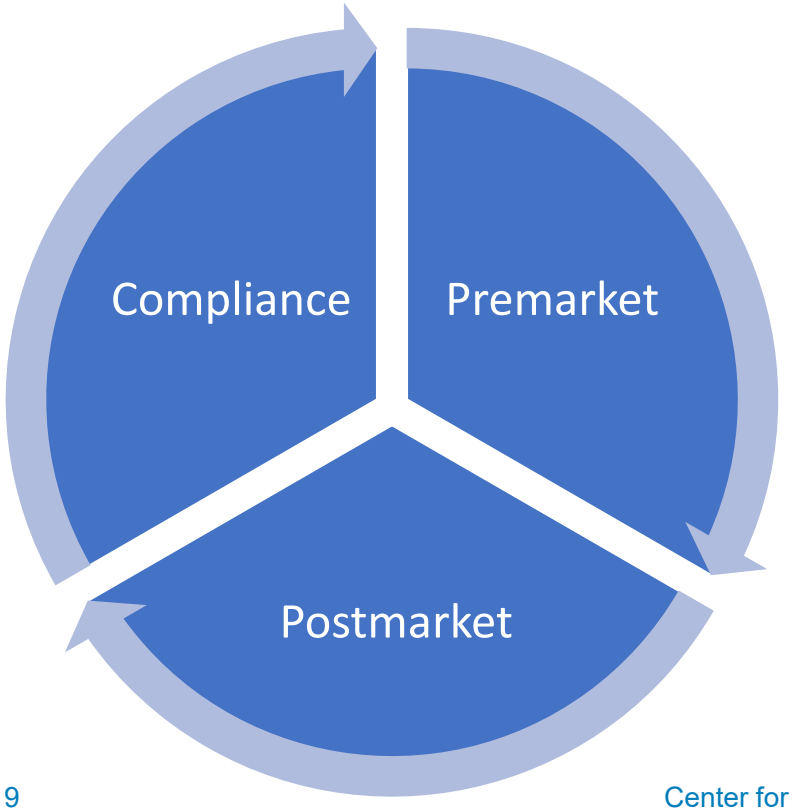


Office of Product Evaluation and Quality

Gynecological and Surgical Devices

			
Endometrial Ablation Devices	Fibroid Treatment Devices	Surgical Mesh for Pelvic Organ Prolapse	Fetal Surgery Devices
			
Hysteroscopes and Gyn Laparoscopes	Colposcopes	Power Morcellators and Containment Systems	Menstrual Hygiene Products

Total Product Lifecycle (TPLC) Review of Medical Devices



Device Definition

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

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

(B) 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

(C) 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)."

Section 201(h)(1) of the Food, Drug, and Cosmetic Act

How to Determine if Your Product is a Medical Device

Policy for Device Software Functions and Mobile Medical Applications (fda.gov)

Device Classification

- Risk-based classification system for medical devices:
  - Class I: Low Risk (general controls)
  - Class II: Moderate Risk (general + special controls)
  - Class III: High Risk (general controls + premarket approval process)
- Controls identify what is necessary to provide a reasonable assurance of safety and effectiveness for a device
- Device classifications are codified in the Code of Federal Regulations (21 CFR 884 addresses Obstetrical and Gynecological Devices)

- Resources available to review and discuss device classifications prior to submitting a marketing application:
  - 513(g) Request for Information: formal device classification decision
  - Title 21 in CFR (21 CFR 884 for gynecological devices)
  - Q-submission program: submit pre-submissions to discuss regulatory strategies, non-clinical, and clinical test plans
  - Digital Health Policy Navigator: Determine whether your software-based application is a medical device

Pre-Submission Program

- Can be used at any stage in your device development (idea, prototype, clinical study design, research and development, etc.)
- Sponsor can submit multiple pre-submissions throughout device development
- Help facilitate more timeline and efficient FDA reviews of marketing submissions

- Resources available regarding Pre-Submissions and public learning modules:
  - CDRH Learn: multi-media educational resources for understanding CDRH basics
  - Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (Guidance)

Investigational Device Exemption

- Limited to studies conducted in the US for significant risk devices (defined in 21 CFR 812.3(m))
- IDE studies can include first-in-human, early feasibility, pilot, feasibility, and pivotal studies
- FDA provides study design considerations and future considerations for a future marketing application as part of an IDE decision

- Resources available regarding IDE content and formatting:
  - IDE Regulations under 21 CFR 812
  - FDA webpage for IDE submission information
  - Q-submission program: submit pre-submissions to discuss regulatory strategies, non-clinical, and clinical test plans
  - Significant/Nonsignificant Risk Medical Device Studies Information Sheet
  - FDA Decisions for Investigational Device Exemption Clinical Investigations (Guidance)

Premarket – 510(k)

- 3,500-4,000 per year across OPEQ
- Demonstrate the device is as safe and effective as a legally marketed predicate device.
- Device is substantially equivalent when it:
  - Has the same intended use as the predicate device;
  - Has the same technological characteristics as the predicate device or the differences do not raise different questions of safety or effectiveness; and
  - Performance data demonstrate the device is as safe and effective as the predicate device

- Resources available regarding 510(k) content, planning, and formatting:
  - 510(k) Database: Includes SE packages for 510(k) cleared devices
  - FDA webpage for 510(k) information and fees
  - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (Guidance)
  - Q-submission program: submit pre-submissions to discuss regulatory strategies, non-clinical, and clinical test plans

Premarket – De Novo

- <100 per year across OPEQ
- De Novo assesses whether general controls and special controls are sufficient to provide a reasonable assurance of safety and effectiveness
- De Novo granted devices can serve as predicate devices for future 510(k) submissions
- De Novo granting includes generating a new regulation with special controls identified

- Resources available regarding De Novo content, planning, and formatting:
  - De Novo Database: Includes granting packages for De Novo granted devices
  - FDA webpage for De Novo information and fees
  - De Novo Classification Process (Evaluation of Automatic Class III Designation) (Guidance)
  - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications (Guidance)
  - Q-submission program: submit pre-submissions to discuss regulatory strategies, non-clinical, and clinical test plans

Premarket – Premarket Approval (PMA)

- <100 per year across OPEQ
- Existing device regulations may already identify a device type as Class III
- PMAs are for high-risk devices and typically rely on clinical data
- PMA review process include pre-approval inspections for the manufacturing facilities
- PMA devices require annual reporting and may be subject to postmarket mandated studies
- Panel review may be part of the review process for a first of a kind devices

- Resources available regarding PMA content, planning, and formatting:
  - PMA Database: Includes original and supplement approvals, including Summary of Safety and Effectiveness (SSED) for original PMA approvals
  - FDA webpage for PMA information and fees
  - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications (Guidance)
  - Q-submission program: submit pre-submissions to discuss regulatory strategies, non-clinical, and clinical test plans

Breakthrough Device Designation

- Statutory criteria for breakthrough designation:
  - (1) The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or condition
  - (2) The device also meets at least one of the following:
    - (a) Represents breakthrough technology
    - (b) No approved or cleared alternatives exist
    - (c) Offers significant advantages over existing cleared or approved alternatives
    - (d) Device availability in the best interest of patients
- Devices granted breakthrough have additional options for FDA feedback on device development, including sprint discussions, data development plan feedback, and clinical protocol agreements

Breakthrough Devices Program
Breakthrough Devices Program (Guidance)

Postmarket and Compliance

- Post approval study
- 522 Studies
- Medical Device Reporting (21 CFR 803)
- Recalls
- Inspections
- Allegations