Overview of FDA / CDRH Databases and General Process

Scott Colburn

Director, Office of Readiness & Response

Office of Strategic Partnership and Technology Innovation

Center for Devices and Radiological Health

US Food and Drug Administration

FDA/CDRH/OST/ORR

Agenda

- FDA's mission and structure
- CDRH's mission and structure
- Medical device evaluation process and key tools/databases
- Questions?

U.S. Food and Drug Administration's Mission

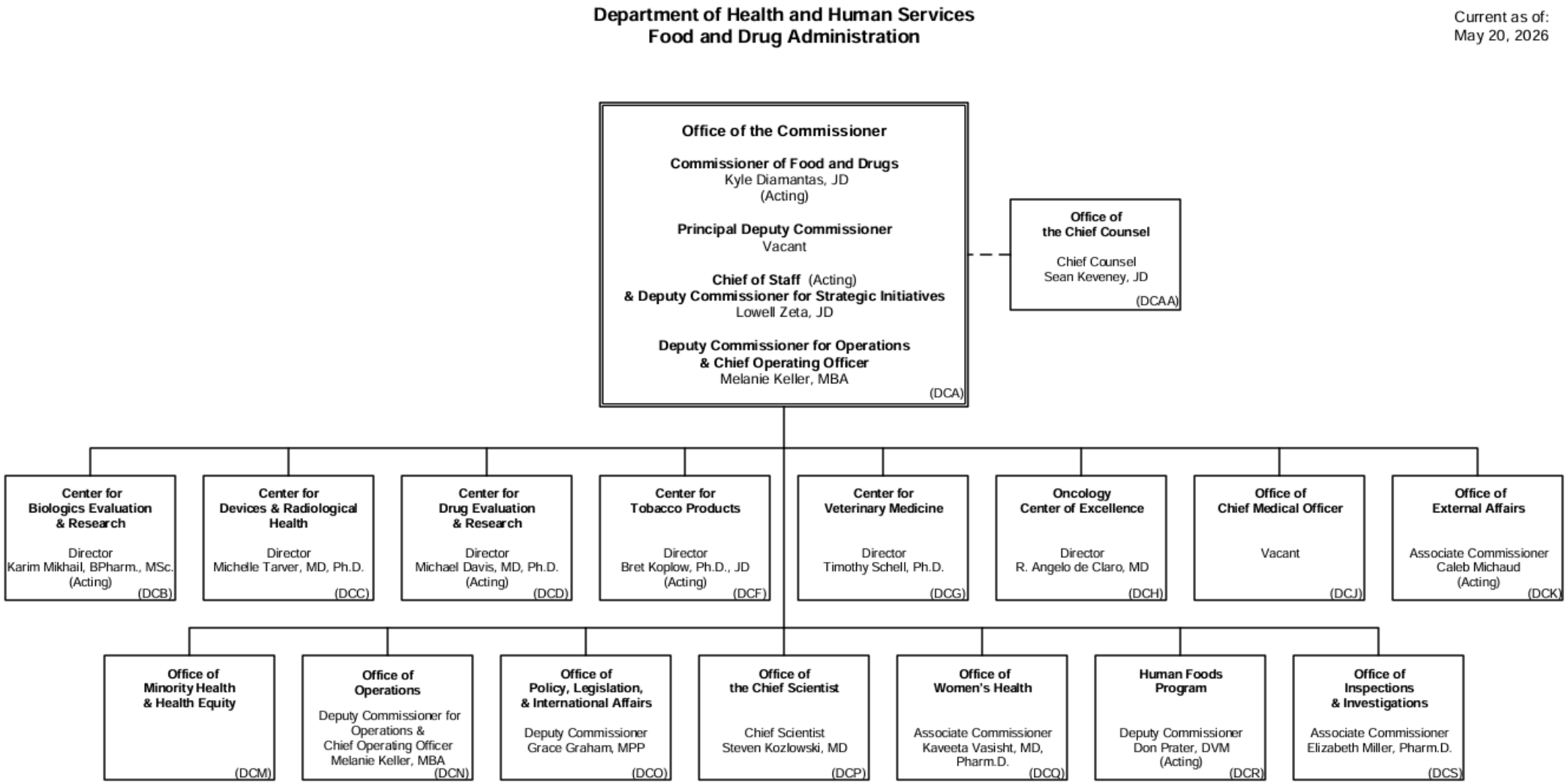
The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Why does the FDA exist?

- FDA formed in 1906 mainly to combat:
  - Adulteration (Meat-packing)
  - Misbranding (Patent medicines)

- FDA authority subsequently increased to include:
  - Evaluation of drug safety prior to approval (1938)
    - Sulfanilamide
  - Evaluation of drug efficacy prior to approval (1962)
    - Thalidomide
  - Premarket approval of medical devices (1976)
    - Dalkon Shield
  - Manufacturing and marketing of tobacco products (2009)

U.S. FDA Organizational Structure

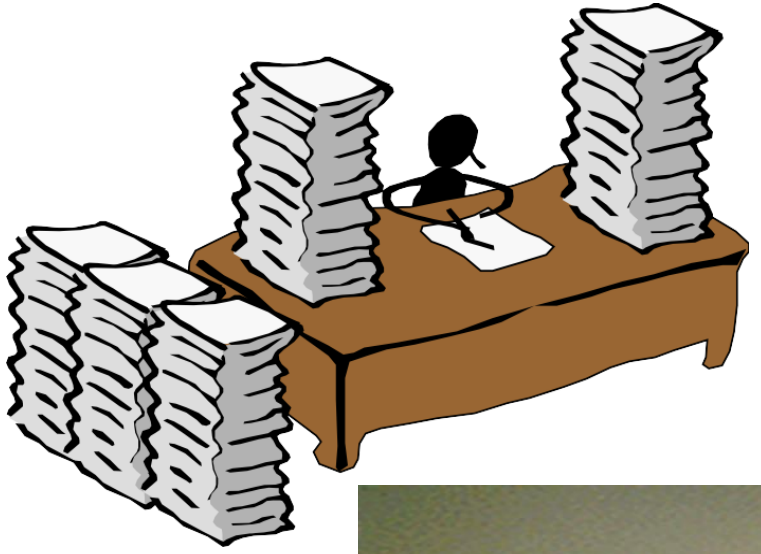


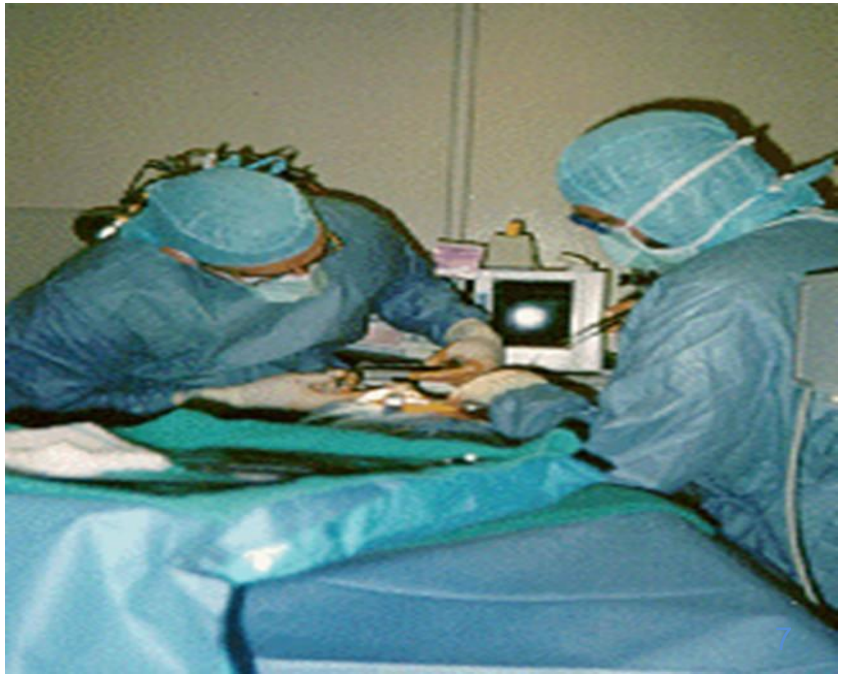
Main FDA Activities

- Product Review and Approval
- Approval of Clinical Studies
- Inspection of Manufacturing Facilities
- Post-Approval Monitoring
- Importing / Exporting
- Basic and Applied Scientific Research
- Education and Outreach

What does FDA not do that you thought we did?

- We don’t test new drugs, vaccines or medical devices -- manufacturers do. We evaluate the data.
- We don’t regulate medical procedures
- We don’t handle intellectual property – this is the job of the U.S. Patent and Trademark Office





CDRH Mission:

to protect and promote the public health.

- Assure that patients and providers have **timely and continued access to safe, effective, and high-quality** medical **devices** and safe radiation-emitting products.
- **Provide** consumers, patients, their caregivers, and providers with **understandable and accessible science-based information** about the products we oversee.
- **Facilitate medical device innovation by advancing regulatory science**, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Day-to-Day Activities at CDRH

- Review medical device and combination product applications
- Evaluate scientific data (engineering tests, lab results, clinical data, etc.)
- Meet with industry and clinical representatives
- Formulate regulatory and scientific policies
- Attend and present at scientific meetings
- Visit manufacturing and clinical study sites

Bringing a Medical Device to Market in the U.S.

- **Step One**
  - **Classify your device and understand applicable regulatory controls**
- Step Two
  - Select and prepare the correct premarket submission
- Step Three
  - Send your premarket submission to the FDA and interact with FDA staff during review
- Step Four
  - Comply with applicable regulatory controls including the establishment registration and device listing

Medical Device Classification

- Device classification depends on the intended use of the device and also upon the indications for use.
- Device classification is also risk based – the risk the device poses to the patient and/or the user is another factor in the class the device is assigned.
  - Class I = lowest risk
  - Class III = greatest risk
- Classification determines the extent of regulatory controls on your device.

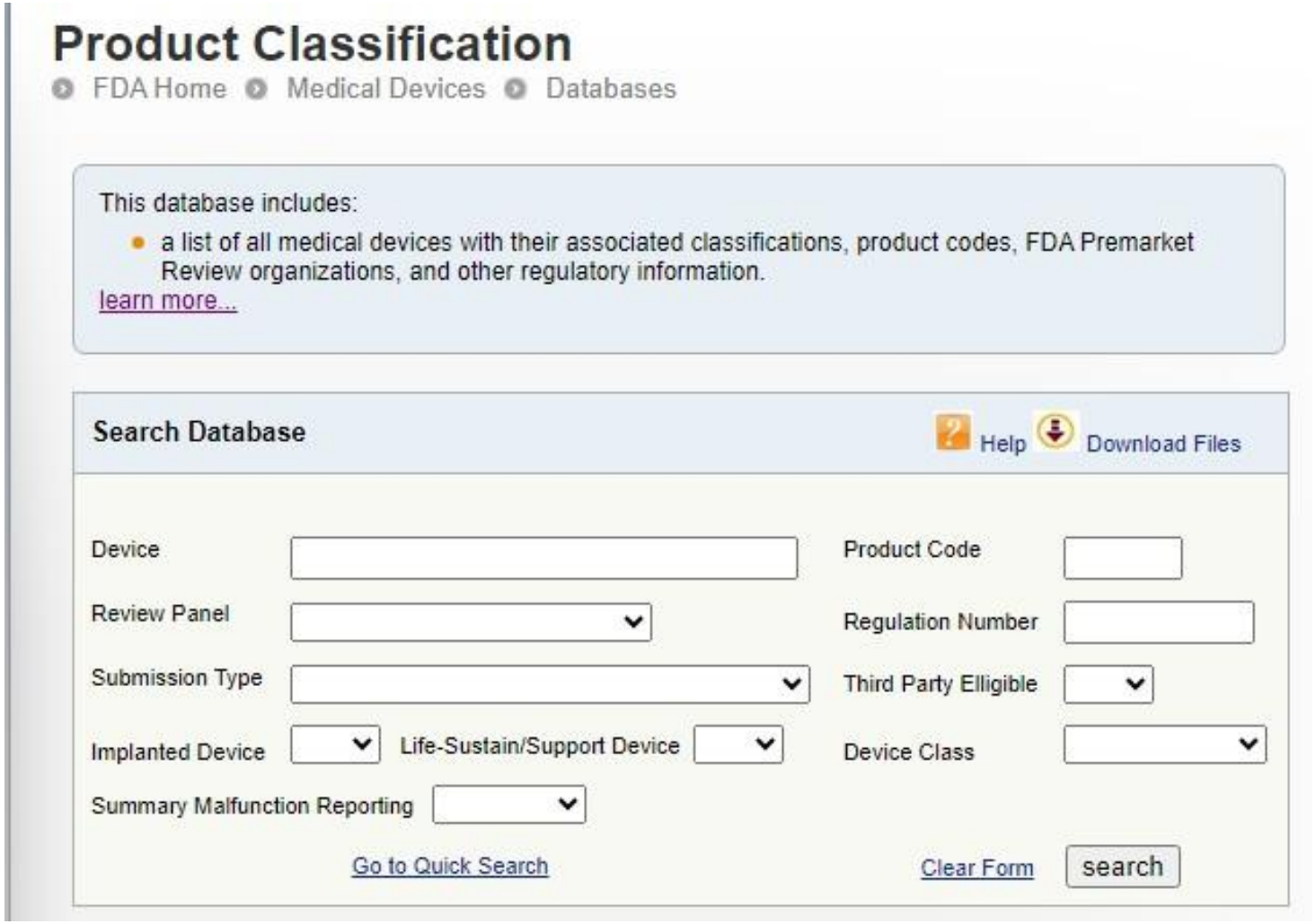
Medical Device Classification

- 1700 generic groups of devices
- Classified within 16 medical specialties
  - 21 CFR 862-892

862 = Chemistry/Toxicology
864 = Hematology/Pathology
866 = Immunology/Microbiology
868 = Anesthesiology
870 = Cardiovascular
872 = Dental
874 = Ear, Nose and Throat
876 = Gastro/Urology
878 = General Plastic Surgery
880 = General Hospital
882 = Neurological
884 = Obstetrical/Gynecological
886 = Ophthalmic
888 = Orthopedic
890 = Physical Medicine
892 = Radiology

Product Classification Database

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm



Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Classification System Risk Categorization

- Class I – Low Risk
  - *General Controls*
- Class II – Moderate Risk
  - *General Controls and*
  - *Special Controls*
- Class III – High Risk
  - *General Controls and*
  - *Premarket Approval*

General Controls

- Regulatory requirements applicable to all devices (unless exempted) outlined in the Food, Drug, and Cosmetic Act and include, for example:

Control	Regulation (21 CFR Part)	Brief Description
Labeling	801	provide information for users
Medical Device Reporting	803	report device-related injuries and deaths
Establishment Registration	807	register business with FDA
Device Listing	807	identify devices
Quality System	820	ensure safe, effective finished devices
Adulteration	FD&C Act 501	contaminated, filthy, putrid, or decomposed substances or intention of committing fraud
Misbranding	FD&C Act 502	provide false or misleading labeling

Special Controls

- Applied when general controls are insufficient
- Usually device specific and include:
  - Performance Standards
  - Postmarket Surveillance
  - Patient Registries
  - Special Labeling Requirements
  - Premarket Data Requirements
  - Guidelines

Class I Medical Devices

- Level of device risk may be sufficiently managed by least amount of regulatory control
  - General Controls
- Typically no premarket submission required
- Device Examples
  - adhesive bandage, I.V. stand, sunglasses

Class II Medical Devices

- General and Special Controls (special labeling, mandatory performance standard, guidelines, etc.)
- Typically requires a 510(k) submission
- Device Examples:
  - syringe, indwelling catheter, powered wheelchair, infusion pump, ventilator

Class III Medical Devices

- Insufficient information exists to assure safety and effectiveness solely through general or special controls
- Typically requires a Premarket Approval (PMA) application or Humanitarian Device Exemption (HDE) application
- Devices that support or sustain human life
- Device Examples
  - heart valves, implantable neuromuscular stimulator, coronary stent

Bringing a Medical Device to Market in the U.S.

- Step One
  - Classify your device and understand applicable regulatory controls
- **Step Two**
  - **Select and prepare the correct premarket submission**
- **Step Three**
  - **Send your premarket submission to the FDA and interact with FDA staff during review**
- Step Four
  - Comply with applicable regulatory controls including the establishment registration and device listing

Submission Types

- Premarket Notification [510(k)]
- Premarket Approval (PMA)
- Humanitarian Device Exemption (HDE)
- Investigational Device Exemption (IDE)

Classification of New Devices

- "New" means that the device has not previously been classified
- By default, these devices are classified into Class III and require PMA approval, regardless of risk
- Regulatory burden may exceed what is necessary

Potential Option: ***de novo***

- Process for new novel devices whose type has not previously been classified which:
  - utilizes a risk-based strategy
  - is used to classify the devices into Class I or II

Bringing a Medical Device to Market

- Step One
  - Classify your device and understand applicable regulatory controls
- Step Two
  - Select and prepare the correct premarket submission
- Step Three
  - Send your premarket submission to the FDA and interact with FDA staff during review
- **Step Four**
  - **Comply with applicable regulatory controls including the establishment registration and device listing**

Code of Federal Regulations (CFR) Citations

- **21 CFR Part 807**
  - Establishment Registration and Listing
  - Premarket Notification [510(k)]
- **21 CFR Part 814:** Premarket Approval (PMA)
- **21 CFR Part 812:** Investigational Device Exemptions
- **21 CFR Parts 801, 809, 812, 820**
  - Medical Device Labeling
- **21 CFR Part 820:** QMSR
- **21 CFR Part 821:** Tracking Requirements
- **21 CFR Part 803:** Medical Device Reporting

CFR Online at: CFR - Code of Federal Regulations Title 21 (fda.gov)

Establishment Registration & Medical Device Listing
21 CFR 807

- Electronic Registration of Medical Device Establishments
  - Notification of U.S. Agent for “Foreign” Establishments
- Electronic Medical Device Listing
- Annual Registration Fee (no waivers)

Registration & Listing Database

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Quality Management System Regulation (QMSR)

- 21 CFR 820 states that manufacturers must establish and following quality systems to help ensure their products consistently meet applicable requirements and specifications
- Applies to finished device manufacturers who intend to commercially distribute medical devices
- Covers the design and manufacture of medical devices sold in the U.S.
- Standard for audit of device establishment

Quality Management System Regulation (QMSR)

- On February 2, 2026, FDA published a regulation to amend the device current good manufacturing practice requirements of the QS Regulation to incorporate the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.
- Harmonize quality management system requirements for FDA-regulated devices with requirements used by many other regulatory authorities around the world.

https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr

Medical Device Tracking

- 21 CFR Part 821
- Manufacturers are required to track certain devices from their manufacture through the distribution chain when they receive an order from the FDA to do so.
- Purpose is to ensure devices can be located promptly in commercial distribution
- Information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices

522 Postmarket Surveillance Studies

- Section 522 of the FD&C Act gives FDA the authority to requirement a manufacturer to conduct postmarket surveillance of a class II or class III device that meets any of these criteria:
  - Its failure would be reasonably likely to have serious adverse health consequences.
  - It is expected to have significant use in pediatric populations.
  - It is intended to be implanted in the body for more than one year.
  - It is intended to be a life-sustaining or life-supporting device used outside a device user facility.

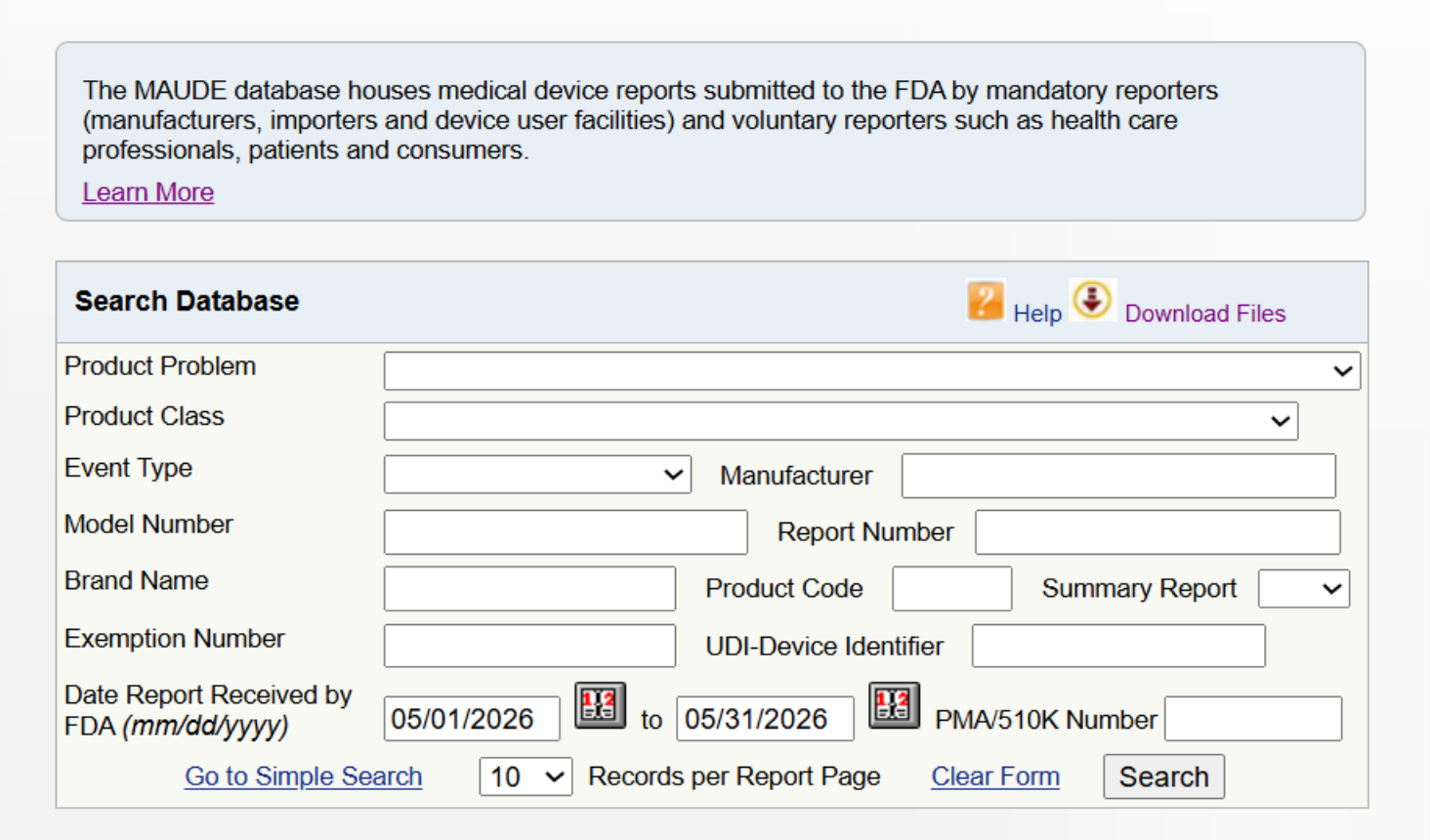
Medical Device Reporting (MDR) 21 CFR 803 "Adverse Event Reporting"

- Mechanism for FDA to identify and monitor medical device adverse events
- **Events:** Death, Serious Injury, and Malfunction
- **Reported by:** Manufacturer, User Facility, and Importers of medical devices

- In accordance with 21 CFR Part 803, manufacturers and importers must submit reports when they become aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Manufacturers must send reports of such deaths, serious injuries and malfunctions to the FDA. Importers must send reports of deaths and serious injuries to the FDA and the manufacturer, and reports of malfunctions to the manufacturer.

Manufacturer and User Facility Device Experience (MAUDE) Database

The Manufacturer and User Facility Device Experience (MAUDE) database contains medical device reports (MDRs) of adverse events. To further promote transparency, the FDA has begun providing additional information in the MAUDE database, such as device and patient problems and patient demographic information. The FDA will continue to seek ways to improve the MAUDE database and the availability of MDR information.



Industry Education Resources

1. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

2. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   http://www.fda.gov/Training/CDRHLearn

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice


FDA
U.S. FOOD & DRUG
ADMINISTRATION