What is a Medical Device?

- An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other article including any component, part or accessory which is:
  - Recognized in the official National Formulary, the United States pharmacopeia, or any supplement to them.
  - Intended for use in the diagnosis of disease or conditions, or in the cure, treatment or prevention of disease.
Devices vs Drugs

- Definition **excludes** products that:
  - Achieve their primary intended purpose through chemical action within the body (drugs)
  - Are dependent upon being metabolized for the primary achievement of their primary intended purpose (drugs)
Examples of Medical Devices

- Surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, stents, orthopedic pins, etc.

- Medical devices also include diagnostic products
  - In vitro diagnostic reagents and test kits (pregnancy test kits, etc.)
  - Imaging systems (MRIs, CTs, etc.)
Key Differences Between Device and Drug Trials

- Investigator Agreement (vs Form FDA 1572)
- Unanticipated adverse device effects (vs AEs)
- Smaller trials, at fewer sites, with smaller budgets
- Pilot and pivotal trials versus phases
- 510(k), IDE (SR and NSR) and PMA regulatory pathway (vs IND and NDA)
Early Device Regulations

- The 1938 Food, Drug & Cosmetic Act initially charged FDA with removing adulterated or misbranded medical devices from the market (but no authority for pre-market review).

- The 1976 Medical Device Amendments gave the FDA more authority after the Cooper Commission determined that more than 700 deaths and 10,000 injuries were associated with medical devices (heart valves, pacemakers, and intrauterine devices). [Public Law 94-295].
Who Regulates Medical Devices in the US?

- The FDA’s Center for Devices and Radiological Health (CDRH)
  - 21 CFR Part 807 (510(k)s)
  - 21 CFR Part 812 (IDEs)
  - 21 CFR Part 814 (PMAs)
Investigational Device Exemptions (IDEs)

- FDA issues IDEs for the study of Significant Risk (SR) devices in order to evaluate safety and/or efficacy.
- May be held by either a sponsor or a sponsor-investigator (SI).
- IRBs (not FDA) approve Nonsignificant Risk IDEs (NSR-IDEs) for devices that do not meet the definition of SR.
  - If IRB disagrees with sponsor, then IDE -> FDA.
Significant Risk vs Nonsignificant Risk Devices

An SR device poses a “potential for serious risk to the health, safety, or welfare of a subject.” A device is SR (and requires an IDE) if it:

- is intended as an implant, or
- is purported or represented to be for a use in supporting or sustaining human life, or
- is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or
- otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
How are Investigational Medical Devices Classified?

- **Class I-III**
  - Helps determine pathway to market
  - 510(k) vs PMA

- **Significant Risk or Nonsignificant Risk**
  - Determines FDA and/or IRB regulatory oversight
Device Classes

- Every medical device is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device.
Device Classes (cont)

- Class I (Lowest Risk)
- Class II (Moderate to High Risk)
  - 510(k) pathway
  - Predicate device (SR or NSR)
- Class III (Highest Risk)
  - PMA pathway
  - No predicate device (SR)

*Risk and regulatory control increases from Class I to Class III*
What about Devices with FDA Clearance/Approval?

- IRB approval is still required before an investigator may conduct a research study using a device with a 510(k) designation or PMA approval.
510(k) Clearance (not approval):

- Over 90% of all devices are marketed via 510(k)s
- Mostly Class I & II, few class III devices
Regulatory Pathway Overview

FDA – CDRH

Exempt

No Clinical Trial

Existing CPT Data

(Class I & II)

510(k)

Clinical Trial Req’d

NSR-IDE IDE

(Class II & III)

PMA
Reporting of Adverse Device Effects

- An investigator shall submit to the sponsor and to the IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but no later than 10 working days after the investigator first learns of the effect.
Medical Device Reports (post-market)

- Manufacturers must review, evaluate, and report all medical device-related reportable events to FDA.

- A report is required when a manufacturer becomes aware of information that reasonably suggests that one of their marketed devices has or may have caused or contributed to a death, serious injury, or has malfunctioned and that the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
What about a New Indication for an Approved/Cleared Device?

- Falls under the IDE regulation
- FDA and/or IRB must review the device for its new investigational application
“Compassionate Treatment Use” of a Device under an IDE

- The FDA provides procedures for the use of an investigational device outside the parameters of an approved protocol. In the case of a serious disease, a device may be made available after the completion of all the clinical trials.

- If an immediately life-threatening disease presents, an investigational device may be made available for treatment use prior to the completion of the research.
A Quick Word about Medicare

- Medicare classifies devices according to categories
  - Category A (Experimental)
    - Procedures typically not covered
  - Category B (Predicate Devices)
    - Procedures typically covered
- NSR devices (NSR-IDEs) are deemed to be in Category B.
Regulatory Pathway Review (one last time)

FDA – CDRH

Exempt

No Clinical Trial

Existing Data

(Class I & II)

510(k)

Clinical Trial Req’d

CPT

NSR-IDE

(Class II & III)

PMA

IDE
Questions?

Thank you!