

# Navigating the FDA, and understanding Medical Device Preemption

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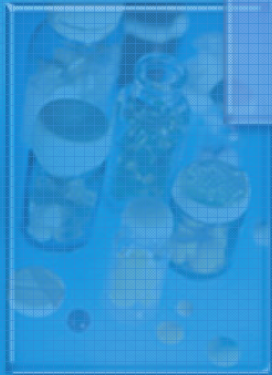
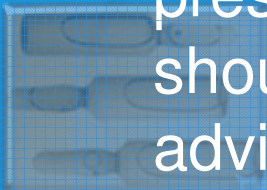
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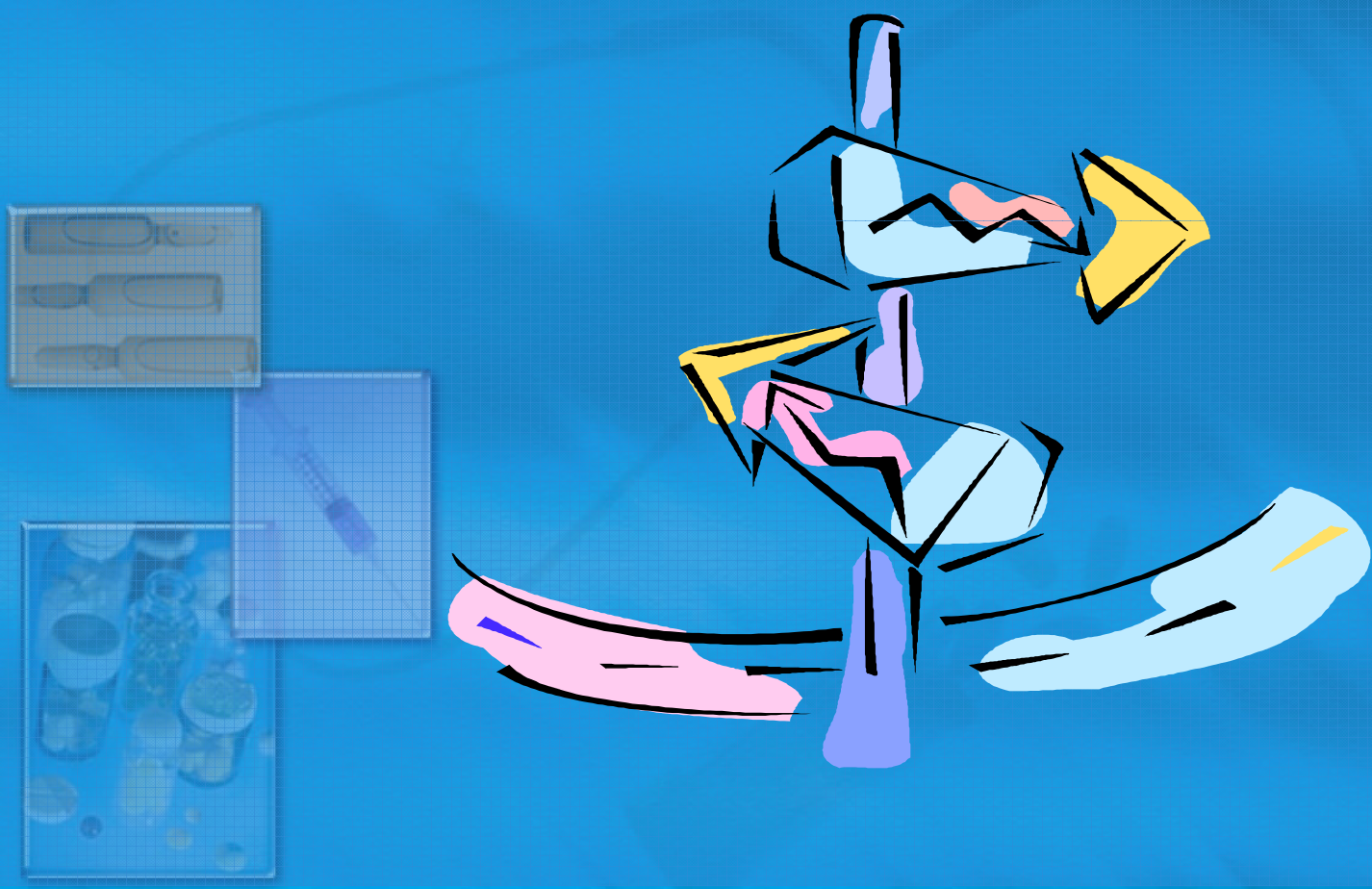


# A bit of Legalese upfront: The Disclaimer

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# Navigating the FDA: Where do I begin?



# Food and Drug Administration Office of the Commissioner

- CDER: Center For Drug Evaluation and Research
- CVM: Center for Veterinary Medicine
- CTP: Center for Tobacco Products
- NCTR: National Center for Toxicological Research
- ORA: Office of Regulatory Affairs
- CFSAN: Center for Food Safety and Applied Nutrition
- CBER: Center for Biologics Evaluation Research
- **CDRH: Center for Devices and Radiological Health**

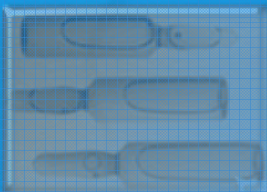


For most device related inquiries you will start with CDRH, but may also deal with CBER if your device deals with blood related products.

# Medical Device Definition

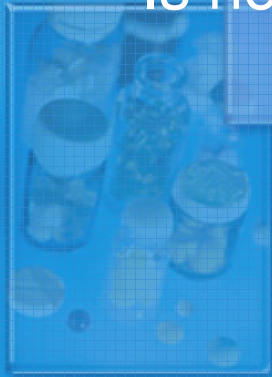
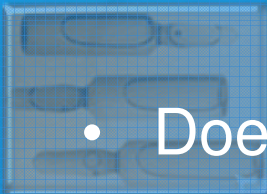
- 21 CFR 201(h)

- If a product is labeled, promoted or used in a manner that meets the following definition of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a **medical device** and is subject to **premarketing** and **postmarketing** regulatory controls.
- A 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, or
    - 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.



# In English Please

- Diagnosis, cure, mitigation, treatment or prevention of disease or condition
- Affects the structure or function of the body
- Does not achieve intended use through chemical action
- Is not metabolized to achieve effect



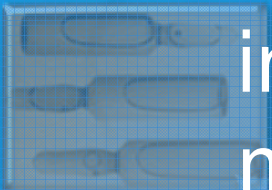
# Device Classifications

- **Class I:** Low risk, general controls, exempt from premarket submissions
  - Crutches, band aids (excluding those intended to speed up healing)
- **Class II:** Higher risk, more complex, premarket notification, 10% require clinical data
  - Wheel chairs, tampons
- **Class III:** Highest risk, life-supporting/sustaining, premarket approval (PMA) with animal/clinical data.
  - Heart valves, lap bands



# General Controls

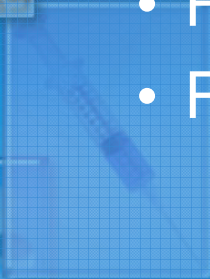
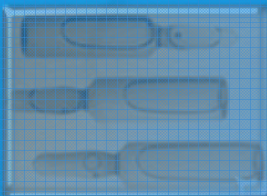
- **General Controls:**
  - These are certain FDA statutory provisions designed to control the safety of marketed drugs and devices. These include provisions on adulteration, misbranding, banned devices, good manufacturing practices (GMP), notification and record keeping, and other sections of the FDA Act found in 21 CFR 360(c) and 513.





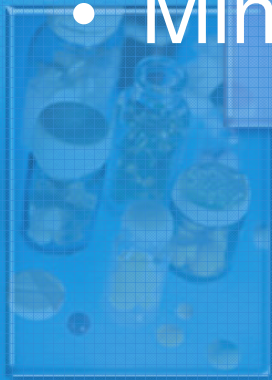
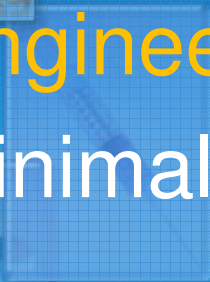
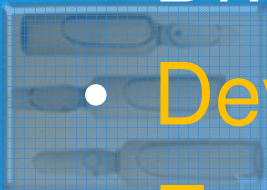
# Devices vs. Drugs vs. Biologics

- I often hear the question: “How do I know if I have a drug, device, or something else?”
  - Answer:
    - Depends
      - On the nature of the device industry
      - Statutory distinctions
      - Regulatory distinctions & similarities
      - Research distinctions & similarities

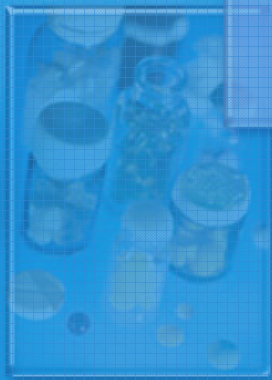
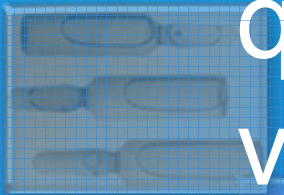


# Nature of the Device Industry

- Entrepreneurial firms common
  - 93% have fewer than 100 employees
  - Mostly venture capitalized
- Diverse and specialized products
- Device “developer” often involved
- Engineer driven
- Minimal clinical trials experience.

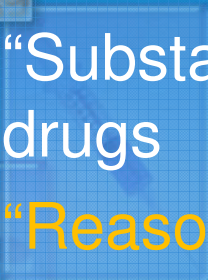
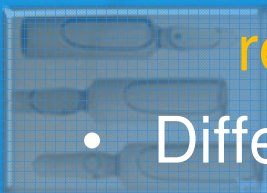


- Shelf life of an average medical device is 18 months.
- Quick rate of change in industry.
- Devices on the market are quickly replaced by newer versions.
- Very important to work with a good patent attorney.



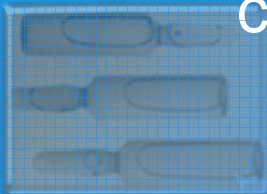
# Statutory Distinctions

- Devices lack market exclusivity provisions
  - Waxman-Hatch (drugs)
  - Orphan drug (drug/biologics)
  - CMS allows for payment for unapproved devices under clinical study whereas drugs generally are not reimbursable.
- Differences in standards approval
  - “Substantial” adequate and well controlled trials for drugs
  - “Reasonable” valid scientific evidence for a device.
- Devices must down regulate
  - Focus at FDA is to reduce cost and time to market.



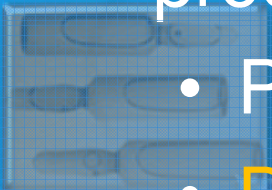
# 510(k) Devices: What is this?

- Not a form. Rather it is a section in Code of Federal Regulations.
  - A medical device that is **substantially equivalent** to a device that was or is being legally marketed is covered by section 510(k) of the FD &C Act.
  - The legally marketed device is referred to as a ***predicate device***.
  - A Sponsor planning to market a substantially equivalent device must submit notification to the FDA **90 DAYS IN ADVANCE** of placing the device on the market.



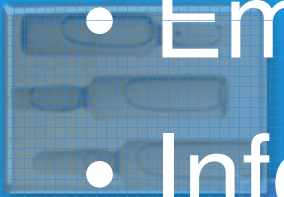
# I'm in my 90 days, now what?

- **No news is good news.**
- If after 90 days you haven't heard anything from the FDA you are cleared to begin marketing your product.
  - Post-marketing requirements
  - **Device pre-emption status for PMA cleared devices.**
    - Means that most state tort law claims for product liability cannot be brought.
    - Result of *Riegel v. Medtronic*



## FDA's Focus in 2010 for Devices

- Community Hospitals
- Institutional Review Boards
- Emergency Use of Devices
- Informed consent issues with devices



## As a Device Sponsor

- Know the regulations or hire someone who does. **Critical!!!**
- Select qualified investigators for PMA trials or 510(k)'s requiring clinical data.
- Obtain feedback on protocol requirements
- Provide adequate training **UP FRONT.**
- Ensure adequate monitoring of the trial
- Bring investigators into **compliance.**



Don't be afraid to ask for help.

