

BME 301

13 - Design, Test, & Sell

Homework

1. What is the main prime mover of a design project?

Customer or Customer needs.

2. What is the IRB and where do you find one?

Institutional Review Board – Found at all place where research is perform using Human Subjects or Animals.

3. What is the function of the FDA with respect to medical devices? What are the classes the FDA uses to define a medical device? What must a developer do to get FDA approval?

The FDA monitors and approves all medical devices. The approval process depends on the type of medical device needing approval.

Here the way the FDA classifies medical devices.

- [Class I](#) - General Controls – Non Life Sustaining - **Most exempt from Pre-Market Notification**
 - Examples of Class I devices include *elastic bandages, examination gloves, and hand-held surgical instruments.*
- [Class II](#) - Special Controls – Non Life Sustaining Most require **-Pre-Market Notification (501k)**
 - Examples of Class II devices include *powered wheelchairs, infusion pumps, and surgical drapes.*
- [Class III](#) - Premarket Approval - Life Sustaining or Life Supporting - **Most require Pre-Market Approval 501k Plus Clinical Data**
 - Class III is the most stringent regulatory category for devices.
 - Premarket approval is the required process of scientific review to ensure the safety and effectiveness of Class III devices.
 - Examples of Class III devices which currently require a premarket notification include *implantable pacemaker pulse generators and endosseous implants.* “

The develop must first determine what classification their medical device falls into and whether the device is equivalent to a device that the FDA has already approved . Then the developed must show **Evidence of performance including both non-clinical and clinical testing and conclusions drawn from these tests.**

4. What are the areas of industrial standards that medical device may have to meet?

- Operational standards
- Safety Standards
- Quality Process

Homework

5. HONORS STUDENTS ADD THE FOLLOWING

Go to the FDA website and research what Device Classification Panels are and how they are used. What is the regulation number for electrocardiograph?

- 1) Go to the FDA website:
- 2) www.fda.gov
- 3) Scroll down and click on Medical Devices
- 4) <https://www.fda.gov/medical-devices>
- 5) Scroll down and click on Device Advice: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>
- 6) Scroll down and click on All Medical Device Databases: Under Product Classifications it states: **that these codes refer to Center of Devices regulation of the particular device.**
- 7) <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
- 8) Scroll down and click on All Medical Device Databases:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm>
- 9) Enter electrocardiograph in the search field and click Search:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/TextResults.cfm>
- 10) Click on electrocardiograph:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=750>
- 11) The registration number is **870 2340**