Al-Mustaqbal University

Biomedical Engineering Department

Class: 4th

Subject: Clinical issues of Biomedical Engineering

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1st term – Lect. 4: Medical device classification.

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Medical devices

Medical devices are products which are used to diagnose, prevent, relieve or treat a disease, disability, injury, etc. There are more than 500,000 different types of medical devices available, covering anything from wheelchairs and glasses to pacemakers, mobile phone apps and state of the art surgical equipment.

Medical device classification

Medical devices are grouped into three classes known as **I, II** and III, with Class I being the lowest risk and Class III being the highest risk. A class I medical device could be a walker, whereas breast implants are class III medical devices.

Medical device classification

- Simple
- Low risk for human use
- General control required

(good manufacturing practices)

Class I

Class I

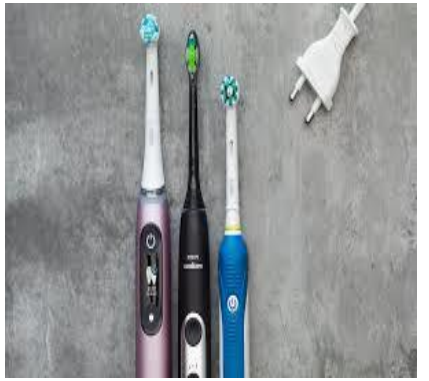
Stethoscopes

Tung Depressors

Reagents used in Clinical Labs

Powered Tooth Brushes

Dental Chair

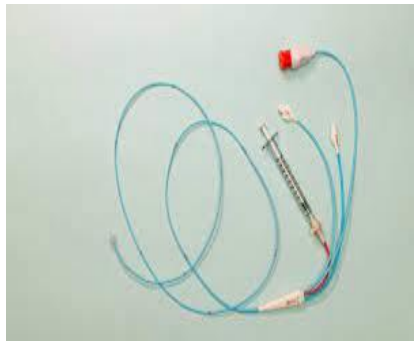


Class I

- Class I devices have minimal contact with patients and low impact on a patient's overall health. In general, Class I devices do not come into contact with a patient's internal organs, central nervous system or cardiovascular system.
- These devices are subject to the fewest regulatory requirements.
- The majority of Class I devices are exempt from Food and Drug Administration (FDA) requirements for Premarket Notification (510(k)) and Premarket Approval (PMA).
- Class I devices are not exempt from FDA General Controls, a series of commands which applies to Class I, II and III medical devices. The provisions of General Controls address adulteration, misbranding, device registration, records and good manufacturing practices.

Class II

- More complex
- Medium risk
- General controls with special controls/they need approval

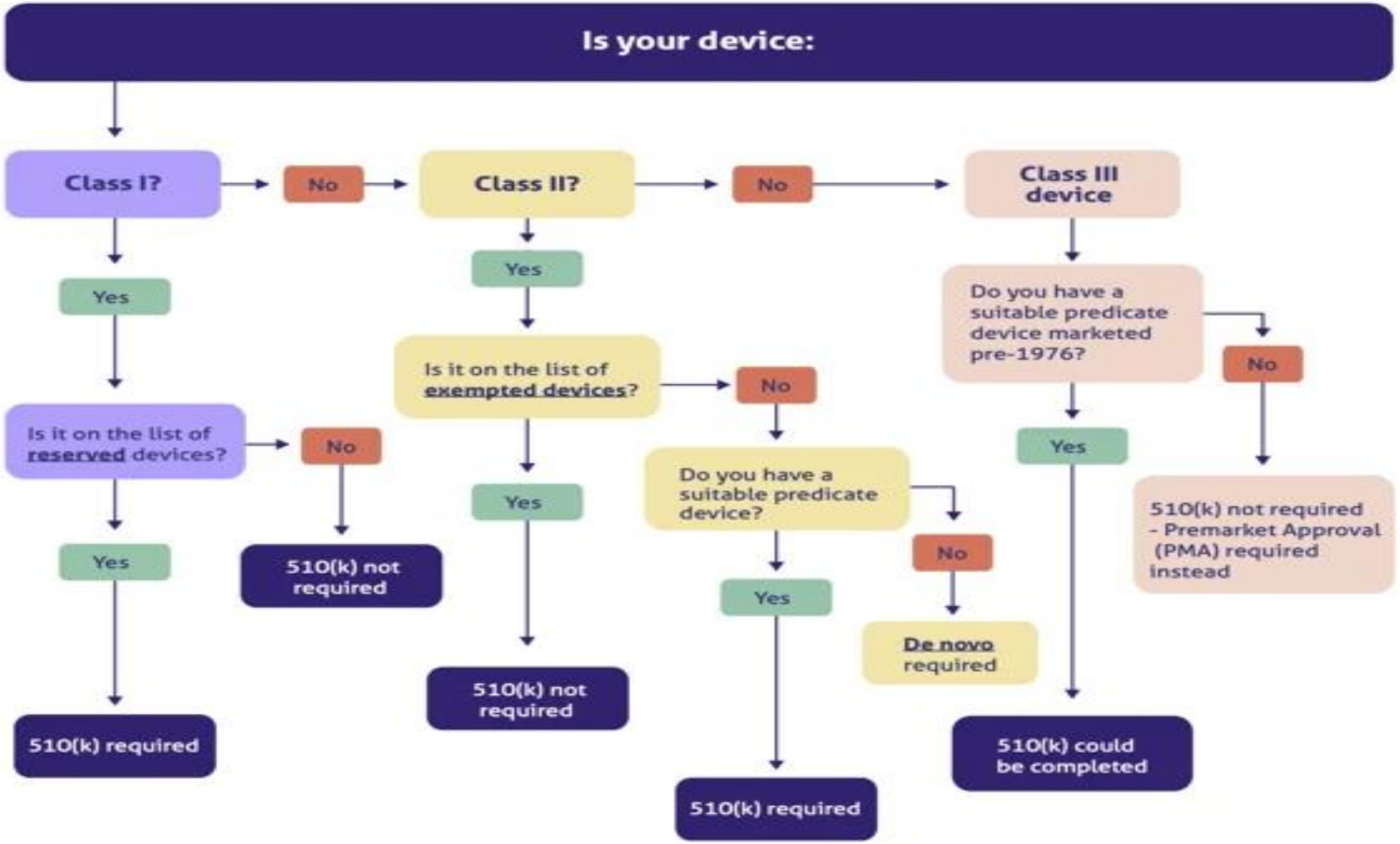


Class II
Catheters
Dental Implants
Biopsy Needles
Ultrasound Imaging System
Powered Wheelchair

Class II

- Class II medical devices are more complicated than Class I devices and present a higher category of risk because they are more likely to come into sustained contact with a patient. This can include devices which come into contact with a patient's cardiovascular system or internal organs, and diagnostic tools.
- Devices for which general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device.
- Most Class II devices come to market using the premarket notification 510(k) process.

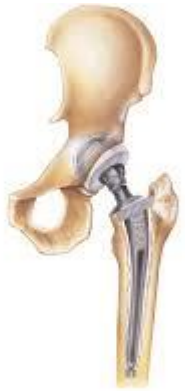
Decision tree map



Class III

- Complex
- High risk (life support)
- Premarket Approval (PMA) needed

Class III
Automatic Defibrillators
Artificial Hip Joints
Heart Valves
Extended Wear Contact Lenses
Left Ventricular Assist Devices



Class III

- Usually sustain or support life, are implanted or present a potential unreasonable risk of illness or injury
- This classification is generally extended to permanent implants, smart medical devices and life support systems.
- Class III devices are subject to all General Controls and the FDA's Premarket Approval (PMA) process. The FDA writes that 'general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices'.

Parameters to classify medical device

1) Duration (length of time the device will be used).
2) Invasiveness (if the device is surgically invasive or not)
3) Active/Implantable (if the device is active or surgically implantable)
4) Medicinal Substances (if the device contain medicinal substances)
5) Risk involvement (risk involved when it is used in patient)

Premarket Notification (510(k)) and Premarket Approval (PMA).

- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective by demonstrating that the device is equivalent to another device which is on the market.
- Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

Good Manufacturing Practices

Good Manufacturing Practices include concerns of organization and personnel; buildings and equipment; controls for components, processes, packaging, and labeling; device holding, distribution, and installation; manufacturing records; product evaluation; complaint handling; and a quality assurance program.

Conformite Europeenne (CE)

- The CE marking (an acronym for the French (“Conformite Europeenne”) certifies that a product has met **European Union (**EU) health, safety, and environmental requirements, which ensure consumer safety.
- The purpose of getting the CE mark for medical devices is to be able to freely market medical devices in the EU, provided that the devices meet any essential requirements

THANK YOU!