PD233: Design of Biomedical Devices and Systems

(Lecture 4)

What is a Medical Device?

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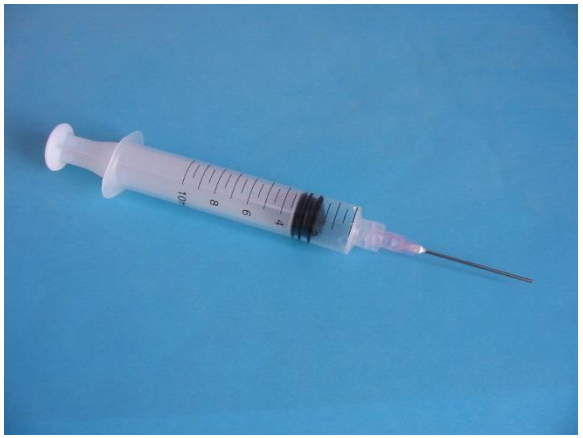
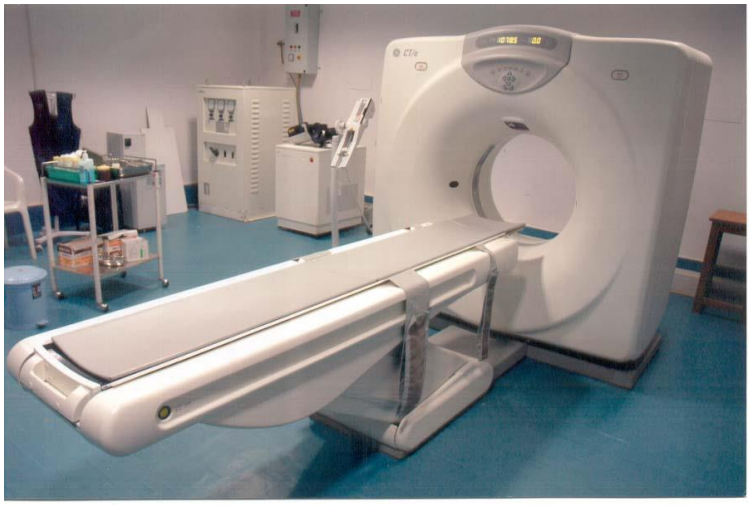
Course Website:
http://cpdm.iisc.ac.in/utsaah/courses/

What is a medical device?





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What is a Medical Device?

Any instrument, appliance, apparatus, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

and which does not achieve its **principal intended action** in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

-Medical Device Directives (common regulation for EU)

Definition by United States- Food and Drug Administration (FDA)

Medical machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory that 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
- Intended to affect the structure or any function of the body of man or other animals,

and **does not achieve any of its primary purpose** through chemical action within or on the body of man or other animals and does not depend on metabolic action to achieve its primary purpose.

India **draft** regulation (2016)

any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of,-

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) disinfection of medical devices;

(vi) control of conception;

which **does not achieve the primary intended action** in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means, and covered under sub-clause (iv) of clause (b) of section 3of the Drugs and Cosmetics Act, 1940 (23 of 1940);

Full draft regulation available at:

http://www.cdsco.nic.in/writereaddata/Draft_Medical%20Devices%20Rules%202016.pdf

Superseded by Medical Device Rules 2017 (notified on Jan 31, 2017 and effective from Jan 01, 2018) – part of Assignment 2

Quiz?

Are these medical device:

- Tooth brushes, dental sticks, dental floss, dental chewing gums
- Baby nappies, mattress protectors
- Contact lenses intended to provide colour to the eyes
- Instruments for tattooing
- Deodorants
- Air conditioner

No unless they make a medical claim – intended use

Medical Device Classification

- Due to large diversity of products and risk associated same regulation cannot be used for all the medical devices – hence the need for classification.
- “Significant risk” is important concept in assessing how the device will be classified and how it will be regulated.
- A significant risk device is a device that presents the potential for serious risk to the health, safety, or welfare of a subject and is (1) intended as an implant, (2) used in supporting or sustaining human life, and (3) of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health.
- A nonsignificant risk device is a device that does not pose a significant risk.

US-FDA classification: Class 1

- **Nonlife sustaining**

- However Premarket approval, registration, device listing, GMPs, and proper record keeping are all required (in United stated)

- E.g. Sethoscope, Tongue depressor

US-FDA classification: Class 2

- Also **nonlife sustaining** but must comply with specific performance standard

- Registration, device listing, GMPs, and proper record keeping are all required (in United stated)
- Usually exempt from the need to prove safety and efficacy

- E.g. sphygmomanometers (BP apparatus), CT machine

US-FDA classification: Class 3

- **Life sustaining**, must comply with specific performance standard
- Need to prove safety and efficacy

- Registration, device listing, GMPs, and proper record keeping are all required (in United stated)

- E.g. pacemaker, heart value, ventilator

How to classify Medical Device under US-FDA system

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

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

Classification under CE Mark (EU markets)

- Rule based classification under Medical Device Directive (MDD)
- Medical Devices are classified as:
  - Class I
  - Class IIa
  - Class IIb
  - Class III

Design controls	Low → High			
EU Class	I	IIa	IIb	III
US Class	I	II		III

- Further directives apply to In-vitro diagnostic (IVD) devices and Active Implantable (AIMD)

Few Definitions:

Time

- **Duration**
- **Transient:** *Normally intended for continuous use for less than 60 minutes.*
- **Short term:** *Normally intended for continuous use for not more than 30 days.*
- **Long term:** *Normally intended for continuous use for more than 30 days.*

Invasiveness

- **Invasive devices :** *A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body*.
- **Body orifice :***Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma*.
- **Surgically invasive device:** *An invasive device which penetrates inside the body through the surface of the body, with the aid of or in the context of a surgical operation*.

- **Reusable surgical instrument**

*Instrument intended for **surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures**, without connection to any active medical device and which can be reused after appropriate procedures have been carried out* (Section 1.3 of Annex IX of Directive 93/42/EEC).

- **Implantable device**

Any device which is intended:

- ***to be totally introduced into the human body or**,*
- ***to replace an epithelial surface or the surface of the eye**,*

by surgical intervention which is intended to remain in place after the procedure.

*Any device intended to be **partially introduced** into the human body through surgical intervention and intended to remain in place after the procedure for **at least 30 days is also considered an implantable device**.*

- **Active medical devices**

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand alone software is considered to be an active medical device.

- Rule 1-18
- MDD_classification_en.pdf

SUBJECTS

- Non invasive devices – Rules 1, 2, 3, 4
- Invasive devices – Rules 5, 6, 7, 8
- Active devices – Rules 9, 10, 11, 12
- Special rules – Rules 13, 14, 15, 16, 17, 18

Implication of Classification:

CONFORMITY ASSESSMENT PROCEDURES	CLASSES					
ANNEXES	I	I Sterile	I measure	IIa	IIb	III
II (+ section 4)						√
II (- section 4)		√	√	√	√	
III					√	√
IV		√	√	√	√	√
V		√	√	√	√	√
VI		√	√	√	√	
VII	√	√	√	√		

Design controls	Low → High			
EU Class	I	IIa	IIb	III
US Class	I	II		III
India	?			

Device classification in India

Four Class Medical Devices (MD) as well as IVD

- low risk - Class A;
- low moderate risk- Class B;

State Govt. Regulated

- moderate high risk- Class C;
- high risk- Class D.

Central Govt. Regulated

Assignment 2

Review the recently issued Gazette notification regulations of medical devices by GoI

Copy available on course website: http://cpdm.iisc.ac.in/utsaah/wp-content/uploads/2016/07/GOI_MedicalDeviceRules_notificationJan2017_eng.pdf

Q1: What is the legal definition of medical device as per this regulation?

Q2: Prepare a flow chart for classifying medical devices as per this regulations.

Due date 6th Sept 2017 – along with 1st Deliverables for the project

For additional credit: Graphical or Interactive tool for medical device classification as per upcoming Indian regulations – deadline 15st Sept.