Risk Classification of Medical Devices*

** Non-IVD medical devices*

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Medical Device Definition

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and doesnot achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

SOURCE: imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.docx

Medical Devices - *Simplified*

Medical Devices	• For Human • Any Instrument/Appliance, etc. • Not primarily by Pharmacological means
Intended Use by Manufacturer	• Diagnoses/Prevention/Monitoring /Treatment • Injury/Diseases/Anatomy/Physiological Processes • *In Vitro* exam for diagnostic purposes
Others	• Sustain life • Control conception • Disinfection of medical devices

Medical Device Classification

Why Classify Medical Devices by Risk?

- To ensure appropriate level of regulatory control depending on risk level of device

- To identify the inherent risks present in each device

Not feasible to subject all medical devices to the most rigorous conformity assessment procedures available.

What Determines a Device's Risk?

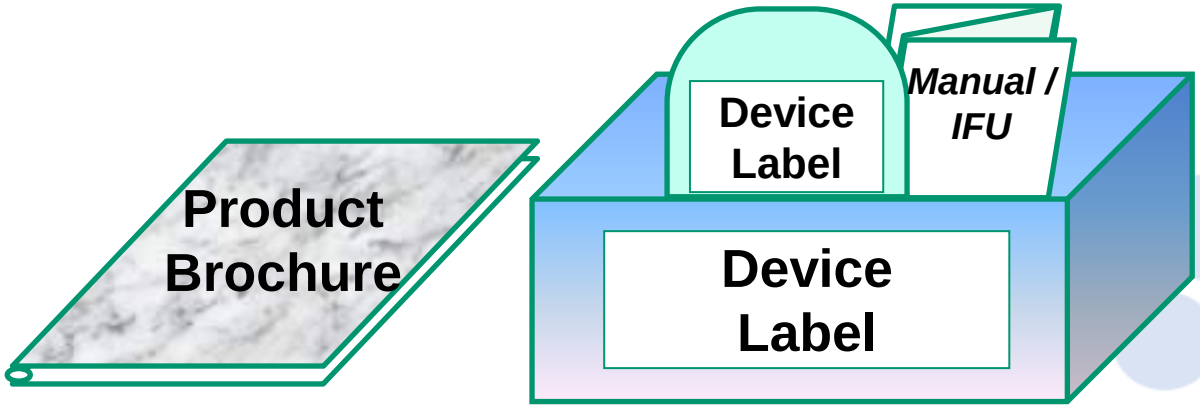
What makes a product fall in a certain risk class?

1) **Intended purpose**
2) **Indications**

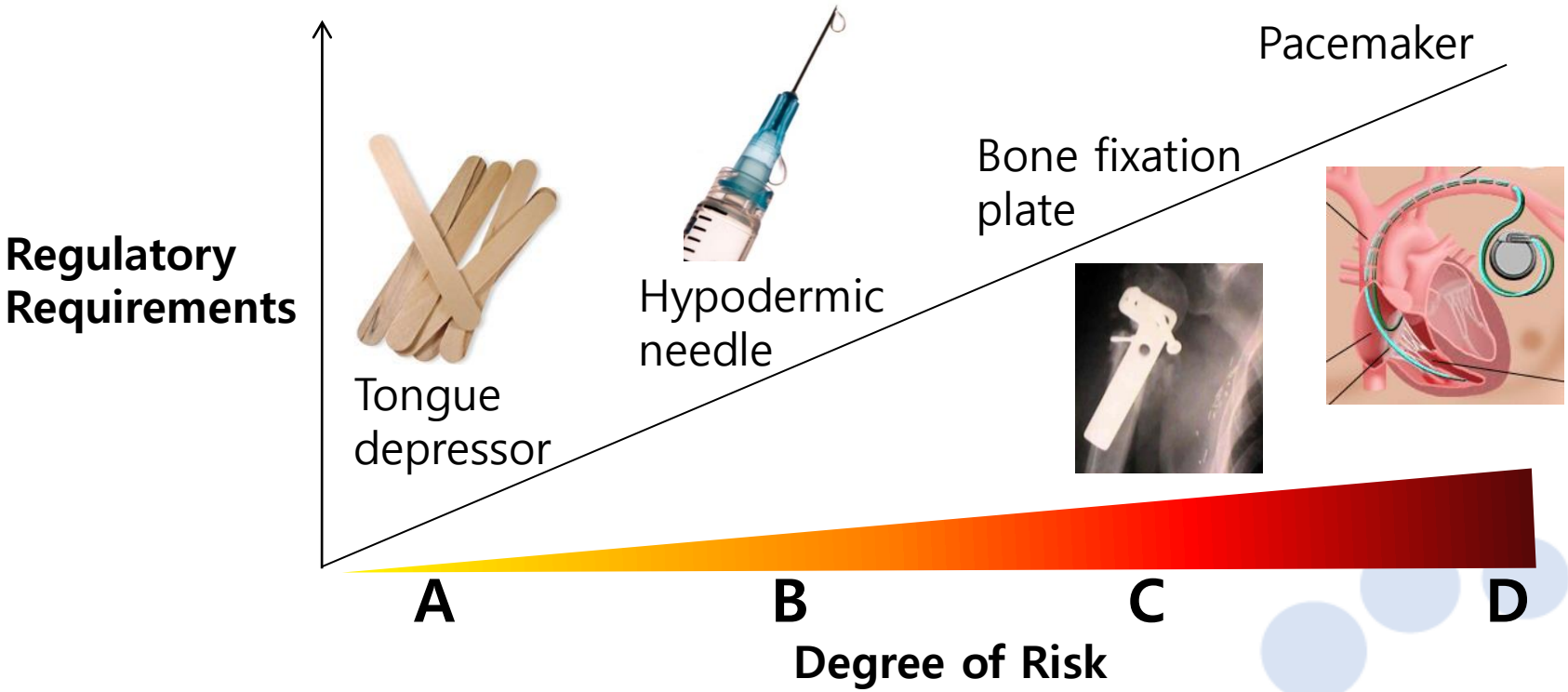
The actual classification of each device depends on the claims made by the manufacturer and on its intended use.

Where can I find the Intended Use & Indications?

- Data supplied by the manufacturer with regards to the device
- On the labelling, in the instructions for use and/or in promotional materials.



Regulatory controls should be proportional to the level of risk of a medical device.



The level of regulatory control should increase with increasing degree of risk.

General Medical Device Risk Classification

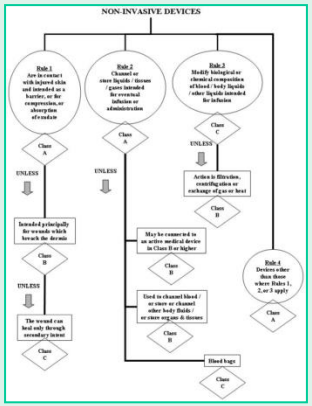
IMDRF Principles of Medical Devices Classification
imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

HSA's Guidance on Risk Classification of Medical Devices
HSA Risk Classification of General Medical Devices
hsa.gov.sg/docs/default-source/medical-devices/gn-13-r2-1-guidance-on-the-risk-classification-of-general-medical-devices-(18sep-pub).pdf?sfvrsn=32a1e2ab_2

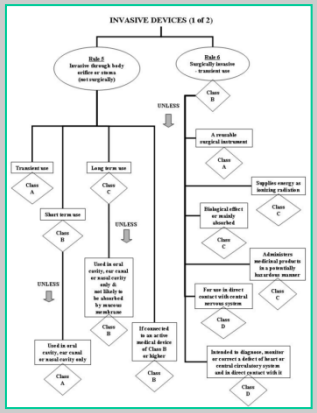
HSA's Medical Device Risk Classification Tool
https://www.hsa.gov.sg/medical-devices/registration/risk-classification

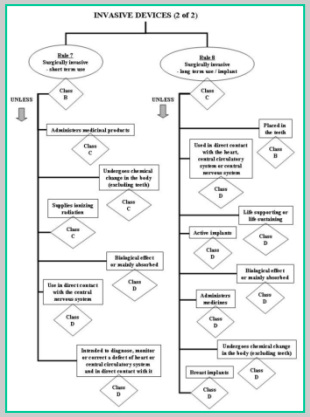
Risk Classification Decision Trees

Non-invasive

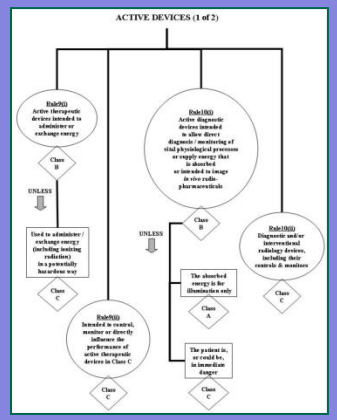


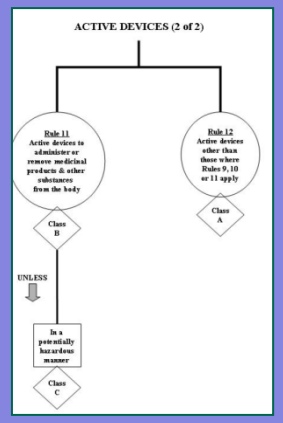
Invasive



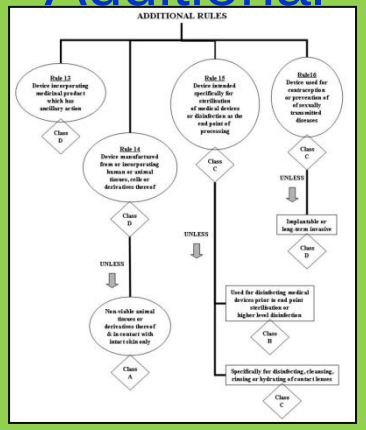


Active





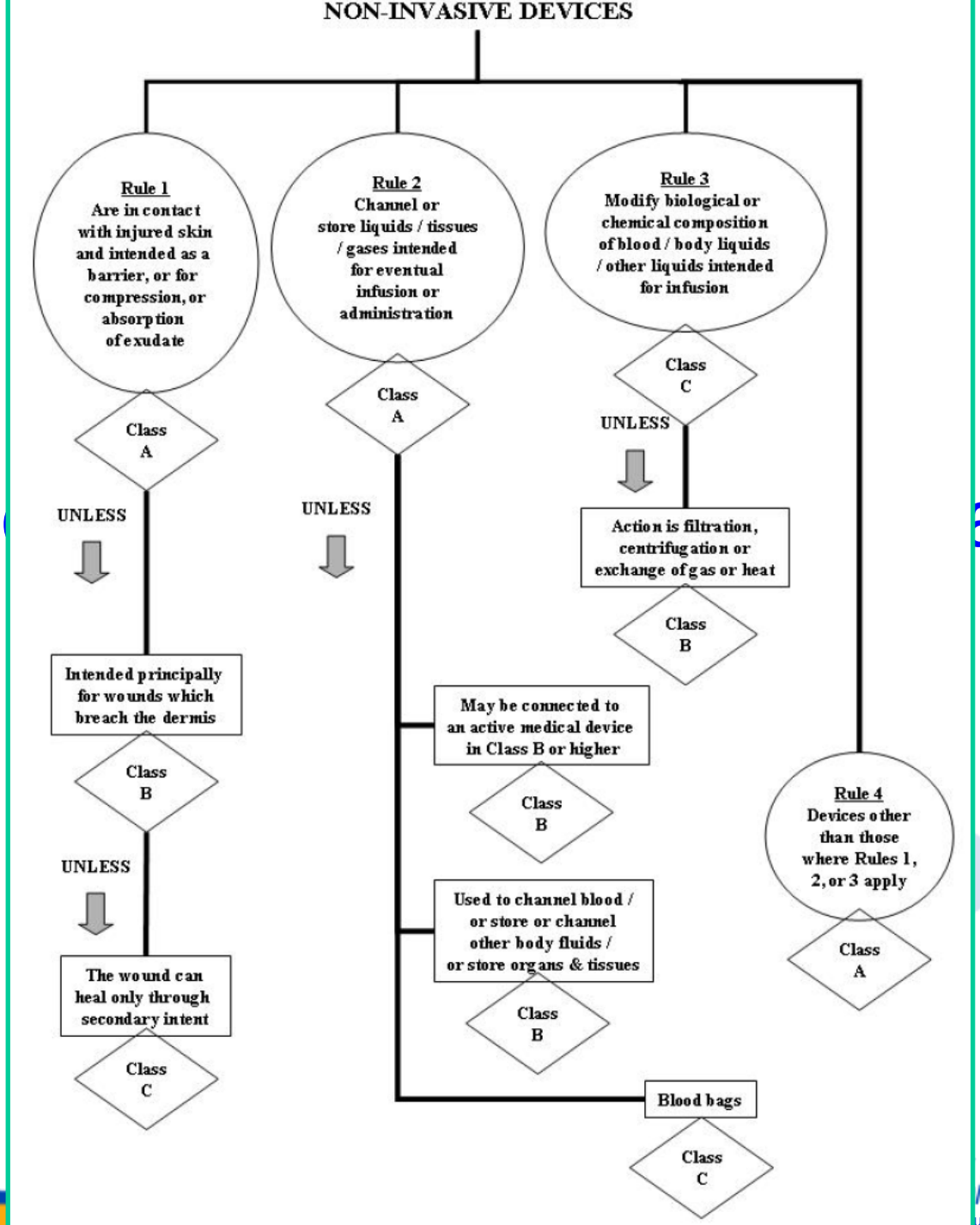
Additional



Found in **HSA Guidance, Appendix A**

- Consult appropriate decision tree
- Find relevant rule within decision tree
- Determine risk class by following tree branches

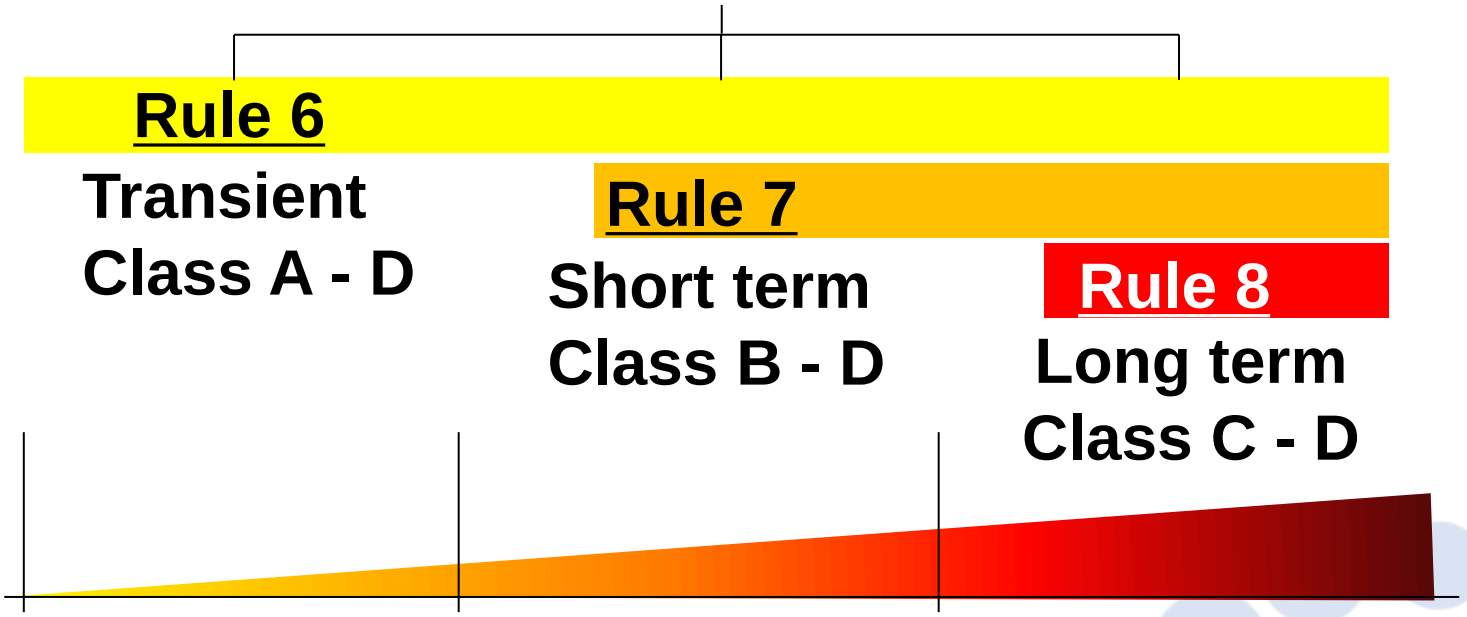
Rul asive



Duration of Device Contact with Body

Surgically Invasive Devices

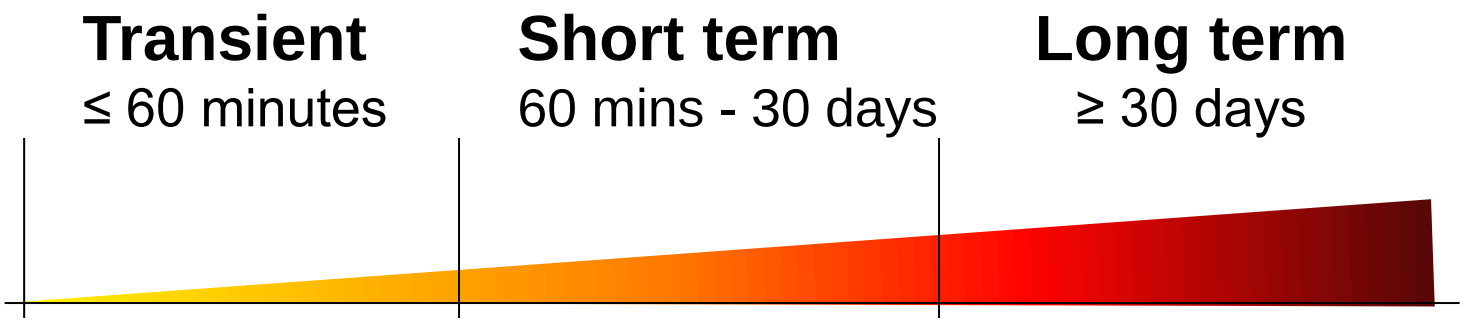
Rules 6, 7, 8



The Risk Class of a medical device is determined by a combination of factors

Duration of Device Contact with Body

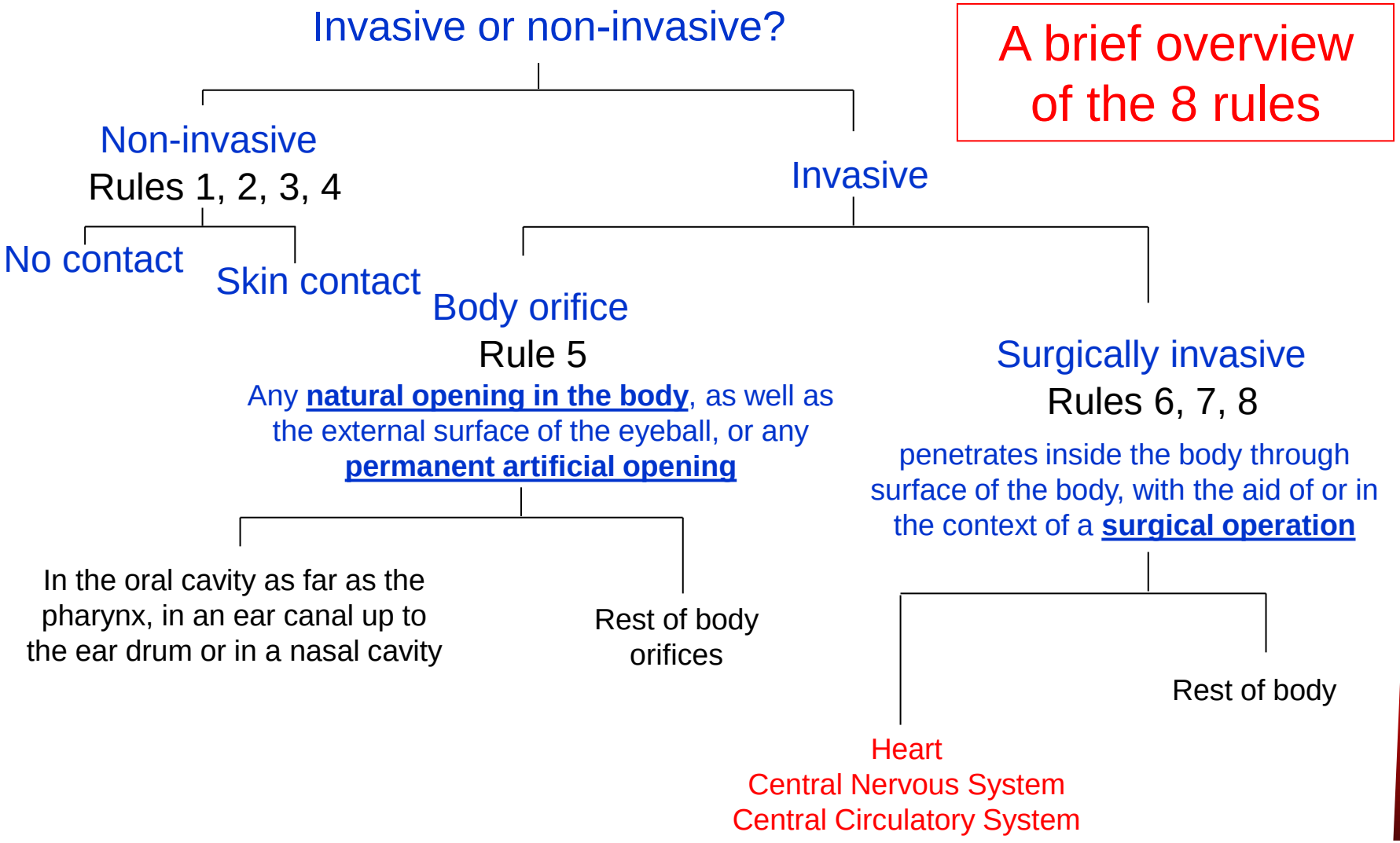
Definitions of contact duration:



Note: If device in use is to be replaced **immediately** by the same or an identical device, this shall be considered as an extension of the continuous use of the device

E.g.: Feeding tubes or uretheric catheters that are routinely replaced

Non-invasive & Invasive



Rules 9-12: Active Devices

Delivery of Energy or Medicinal Products

What is an Active Medical Device?

Operation depends on a source of power not generated directly by the human body or gravity

Active Devices fall into 4 categories:

- Active Therapeutic Devices
- Active Diagnostic Devices
- Active devices intended to exchange substances with the body
- Other Active Devices

Rules 9-12: Active Devices

Active Devices

- Administer or exchange energy
  - Active **Therapeutic** Rule 9
  - Active **Diagnostic** Rule 10
- Administer or remove medicinal products, body liquids or other substances Rule 11
- Others Rule 12

Image Sources: US FDA CDRH 2005 Strategic Plan
Chile APEC Presentation 2006

Active Devices

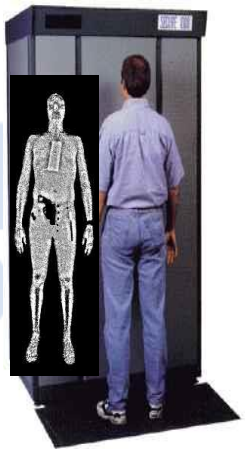
Active Therapeutic Devices (Rule 9):

- Administer or exchange energy - **CLASS B**
  Hearing aids
- In a ***potentially hazardous*** way - **CLASS C**
  Lasers and electrosurgical generators, defibrillators

Image source: Chile APEC Presentation 2006

Active Diagnostic Devices (Rule 10):

- Illuminate with visible or infra-red light - **CLASS A**
  Surgical lamp, examination lights
- Supply ionising radiation - **CLASS C**
  X-rays, radioactive isotope-containing devices



Rule 9 - 'Potentially hazardous'

The term 'potentially hazardous manner' refers to:
characteristics of the device
NOT the competence of the user.

Examples:

Electrical energy	High frequency electrosurgical generators	External defibrillators	Transcutaneous electrical nerve (TENS)
Ultrasound	Lithotriptors	Diagnostic ultrasound	
Light	Class III Lasers (surgical laser)	Intense Pulse Light (Check output, J/cm2)	Dental curing light

Rule 10 – Critical vs Non-critical

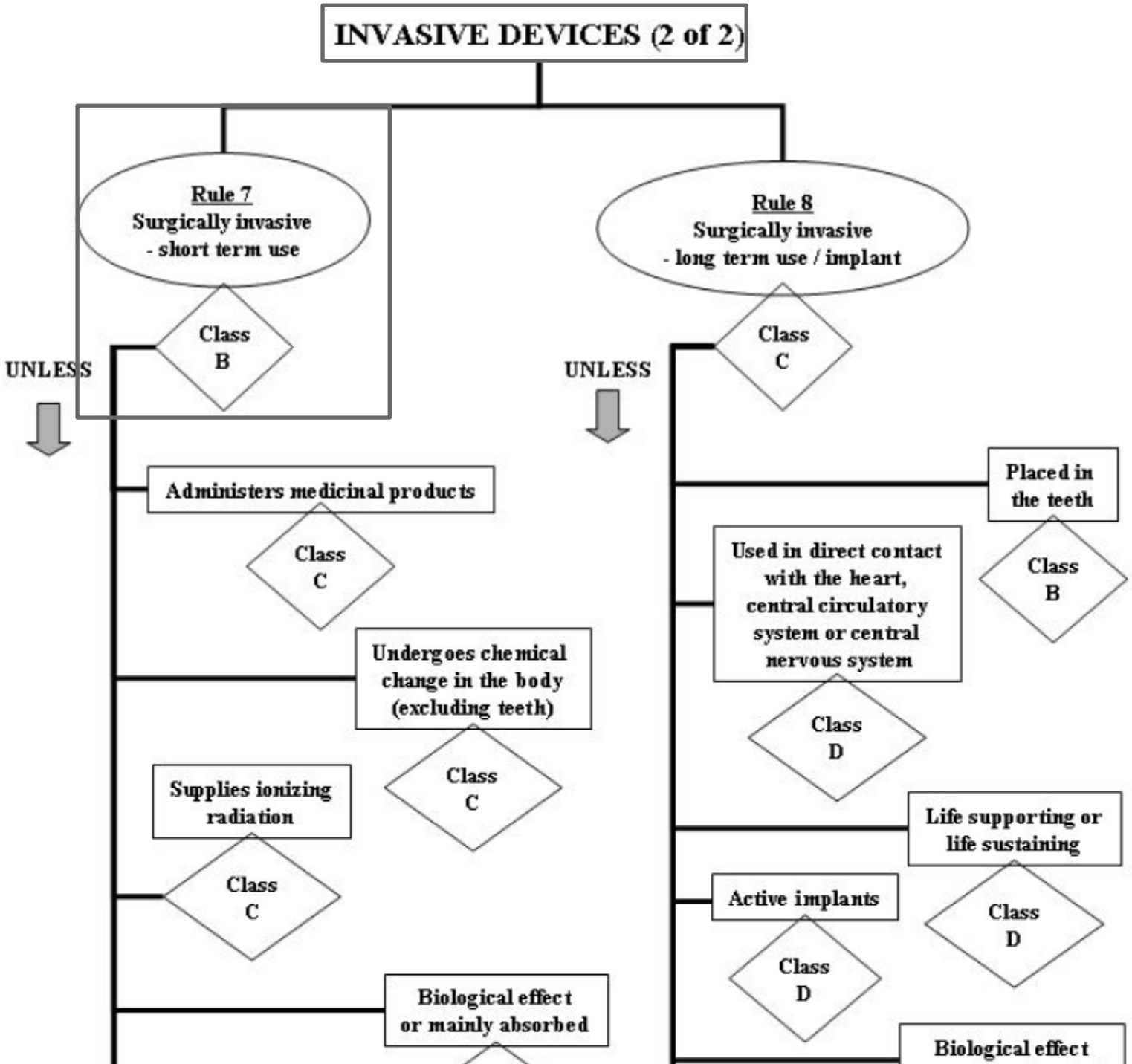
Active Diagnostic Devices that:

Measure vital physiological processes

Vital physiological processes include: respiration, heart rate, cerebral functions, blood gases, blood pressure & body temperature

Non-critical conditions	Critical conditions
Class B	Class C
Routine check ups and in self-monitoring	- Surgery monitoring, intensive or emergency care - Monitors/alarms - Continuous monitoring
Digital thermometers, non-continuous BP monitors	Vital sign monitoring systems

Ex


INVASIVE DEVICES (2 of 2)
Rule 7
Surgically invasive
- short term use
Class
B
UNLESS
Administers medicinal products
Class
C
Undergoes chemical change in the body (excluding teeth)
Class
C
Supplies ionizing radiation
Class
C
Biological effect or mainly absorbed
Rule 8
Surgically invasive
- long term use / implant
Class
C
UNLESS
Placed in the teeth
Class
B
Used in direct contact with the heart, central circulatory system or central nervous system
Class
D
Life supporting or life sustaining
Class
D
Active implants
Class
D
Biological effect

Active devices intended to exchange substances from the body (Rule 11)

- Administer or remove medicinal products, body liquids or other substances - **CLASS B**
- Done in a potentially hazardous manner - **CLASS C**
- Depending on:
  - ❖ Substances involved

    Saline, analgesic, insulin, chemotherapy drugs
  - ❖ Part of the body concerned

    Central nervous system, Systemic circulation
  - ❖ Mode and route of administration

    Intravascular, intraperitoneal, enteral

Image source: US FDA CDRH 2005 Strategic Plan

Other Active Devices (Rule 12)

All other active devices not covered in Rules 9, 10, 11 (Rule 12) - <u>CLASS A</u>

Examples:

- Powered hospital beds & wheelchairs
- Powered equipment for the recording, processing, viewing of diagnostic images
- Dental curing lights

Image source: Chile APEC Presentation 2006

Rules 13-17: Additional Rules

Additional Rules:

Product Type	Rule
Combination Product	13
Non-viable Biological Product	14
Disinfectors/ Sterilisers	15
Contact Lens Solutions	16
Contraceptive	17

Devices Incorporating a Medicinal Product (Rule 13)

- Medicinal product intended to assist function of the device
- Product should not achieve its **primary** intent by pharmacological, immunological or metabolic means

  (If it does, it is not a medical device!)
- Special **CLASS D** medical device

Medical Device + Registrable Medicinal Product

↓

Device-Drug Combination Product

E.g. Silver-incorporated dressings, drug-eluting stents/balloon catheters, dermal fillers with anaesthetics

“My medical device contains a well-established medicinal product”

The intended use of a medicinal product incorporated in a medical device may differ from its approved use as a medicinal product alone.

Aspirin
Pain relief
Regulatory approval in 1980

+

Coronary Stent
Regulatory approval in 1986

COMBINATION

Aspirin-coated Stent
Aspirin is intended to promote tissue healing process

Different intended use

Image source: Chile APEC Presentation 2006

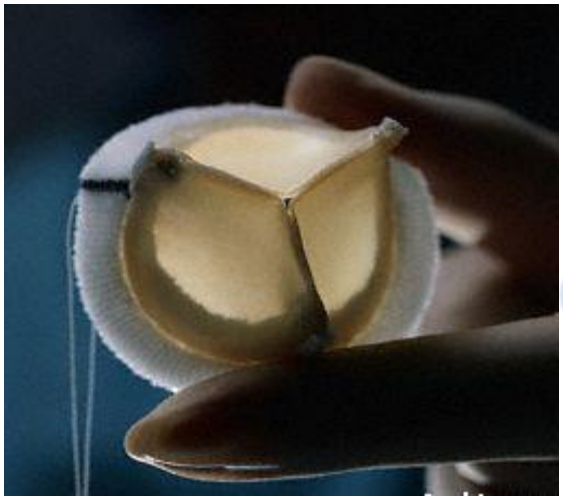
Biological Products (Rule 14)

Devices incorporating non-viable cells, tissues or derivatives from animal, microbial or recombinant origin

- Examples: collagen, heparin, hyaluronic acid
- Risk of disease transmission

  e.g. Bovine Spongiform Encephalopathies

  Incurable, Death
- Thus **CLASS D**



Source: Chile APEC Presentation 2006

Disinfectors/ Sterilisers (Rule 15)

Intended for disinfection / sterilisation of medical devices

Washer disinfectors & Autoclaves

- Not end-point disinfection - **CLASS B**
- **End-point** disinfection / sterilisation - **CLASS C**

Risk of disease transmission

Safety & efficacy of sterilisation equipment is crucial

Source: Chile APEC Presentation 2006

Contact Lens Solutions (Rule 16)

Intended for disinfecting / cleaning / rinsing / hydrating contact lenses - CLASS C

Risk of infection or irritation to eye

Efficacy the contact lens solutions crucial in ensuring safe use of contact lens

Source: Chile APEC Presentation 2006

Contraceptive devices (Rule 17)

- Prevention of contraception and/or sexually transmissible diseases, e.g.

  Condoms, intra-uterine contraceptive devices

- Transient or short term - **CLASS C**,
- Long-term or implantable – **CLASS D**

Image source: Chile APEC Presentation 2006

Who Classifies?

Risk Class is determined by:

- The intended purpose assigned by the manufacturer to the device
- The highest possible applicable class, If a device can be classified according to several rules

NOT

- The class assigned to other similar products
- The particular technical characteristics of the device

E.g.: 2 sutures that have the same composition may well have different intended purposes

Steps to Risk Classification

1. Product owner's intended use & indications
2. Determine characteristic of device:

Section	Rules
Non-invasive (incl. skin wound)	1 – 4
Invasive	5 – 8
Active devices	9 – 12
Additional rules - Combination - Biological - Disinfector/Steriliser - Contact Lens Solution - Contraceptive	13 – 17

3. From all applicable rules, highest risk class is to be assigned.

Device claims examples

Catheter

- Claim 1:

  For transient use…
- Claim 2:

  … and directly placed into the superior vena ca

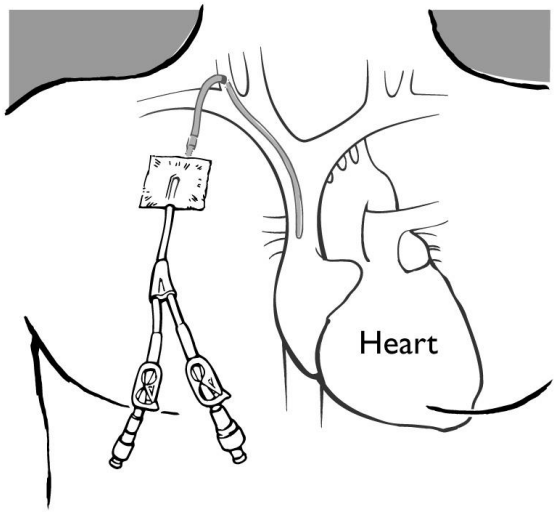
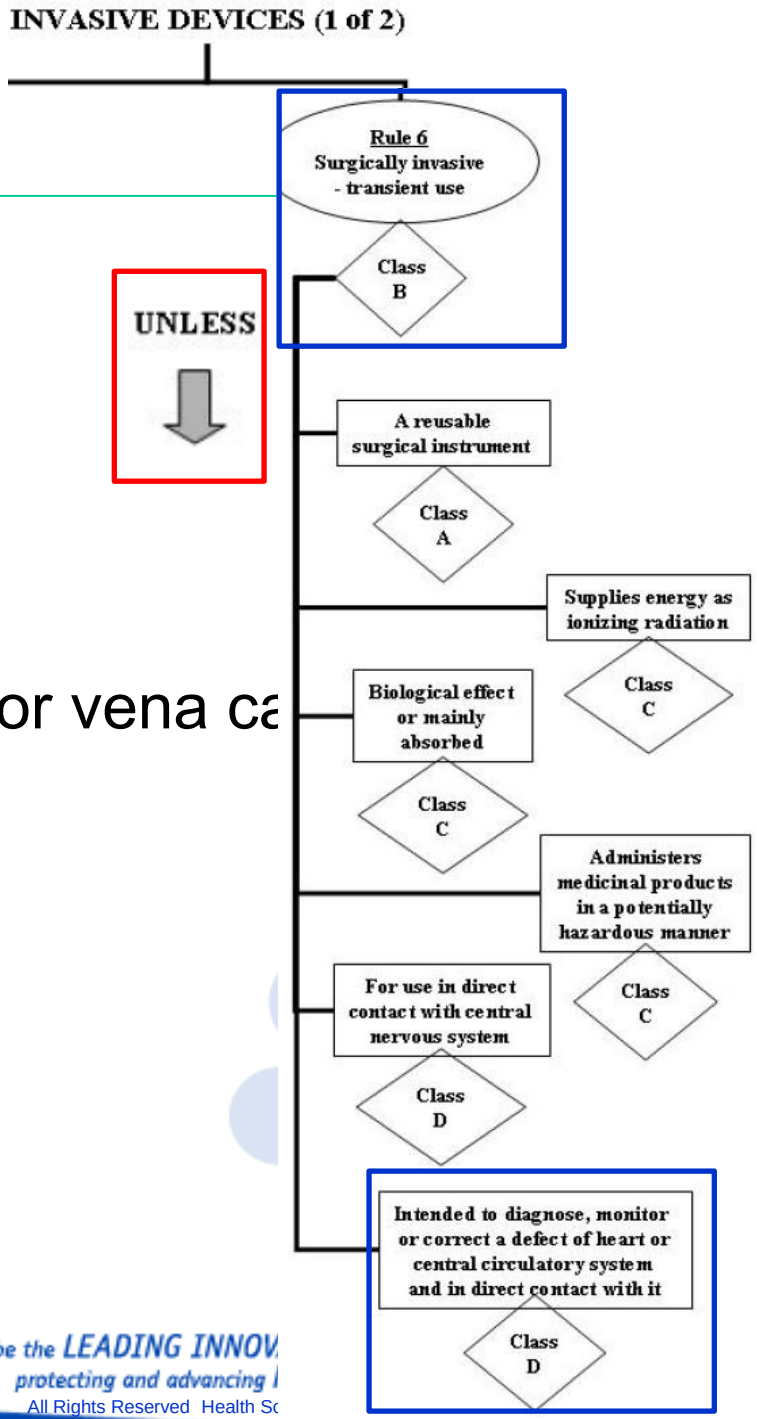


Image source: http://uwmedicine.washington.edu



Device claims examples

EEG monitor

- Claim 1:

  Active diagnostic device to characterize
- Claim 2:

  …with electrodes directly implanted into

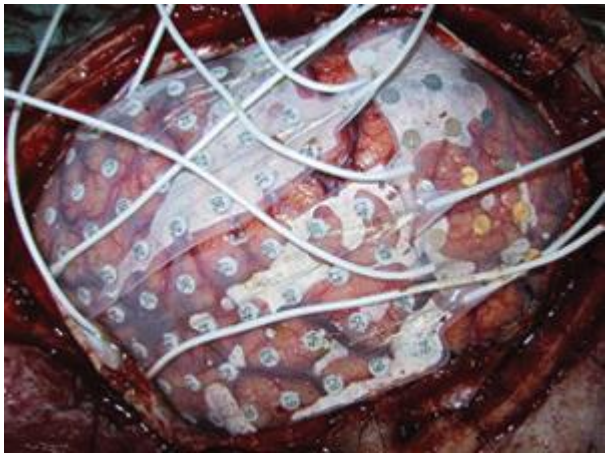
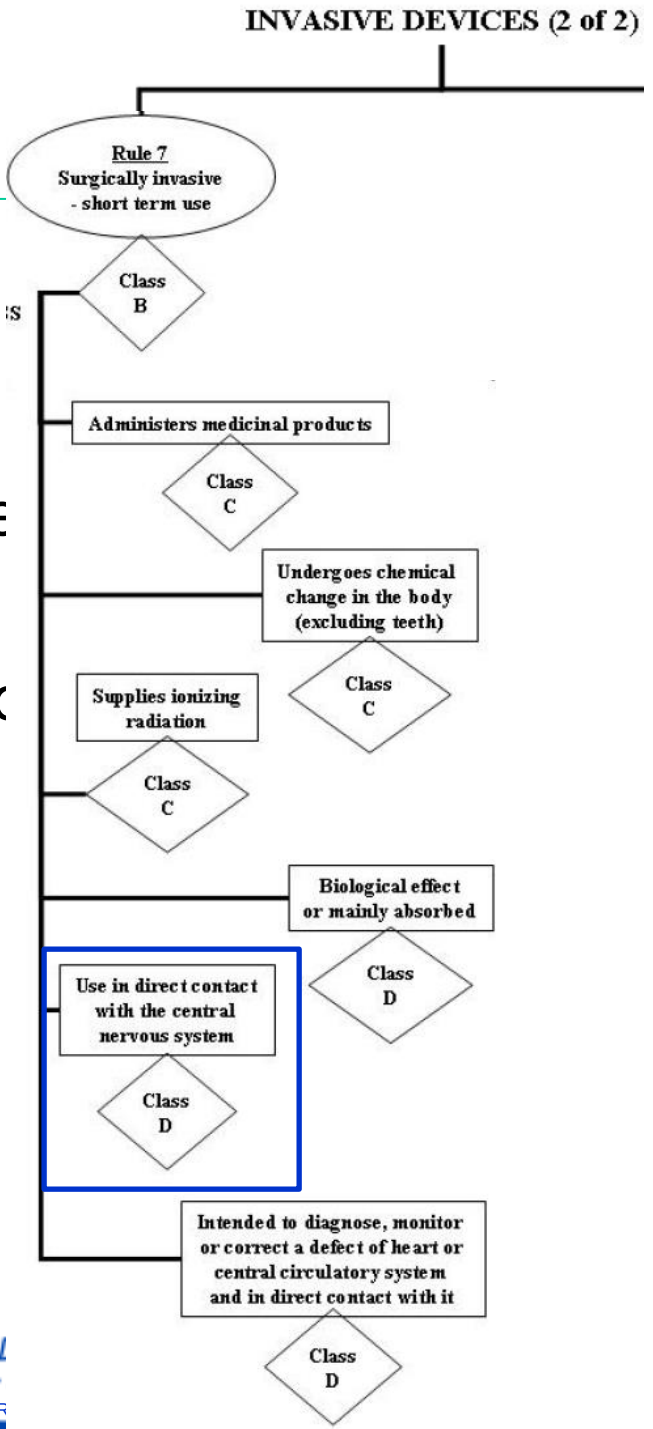


Image source: www.chw.org



Thank You