**Making a Comprehensive Inventory of Medical Devices Marketed in the U.S.**

**Definition:**<https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels>

1. Anesthesiology
2. Cardiovascular
3. Chemistry/Toxicology
4. Dental
5. Ear, Nose, and Throat
6. Gastroenterology and Urology
7. General and Plastic Surgery
8. General Hospital
9. Hematology/Pathology
10. Immunology/Microbiology
11. Neurology
12. Obstetrical and Gynecological
13. Ophthalmic
14. Orthopedic
15. Physical Medicine
16. Radiology

**Classification:**<https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>

<https://www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes-2/>

1. Class I: medical device are those devices that have a low to moderate risk to the patient and/or user
2. Class II: medical device are those devices that have a low to moderate risk to the patient and/or user
3. Class III: medical devices are those devices that have a high risk to the patient and/or user, and usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury

**Medical Device Definition**

<https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device>

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. 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
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve 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 its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

<https://www.fda.gov/medical-devices/classify-your-medical-device/download-product-code-classification-files>

**Flow chart about the process FDA approves a device**

<https://www.fda.gov/media/82395/download>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K050084>

PMA: may not have all the data

**Device Classification Stuff**

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>

<https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>

<https://www.fda.gov/patients/device-development-process/step-3-pathway-approval>

<https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices>

<https://www.fda.gov/medical-devices/overview-device-regulation/code-federal-regulations-cfr>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm>

**Theory**

From Product code: KWA

1994: a lot of 510(k) stuff made exempt

**HDE**

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm>