Guide to FDA Device Classification

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New Medical Product or Device

START HERE

Device classification is determined by:

- risk to patient and/or user
- intended use
- indications for use

Is the device intended to:

- support or sustain human life
- prevent impairment of human health
- support vital organs or cardiovascular system?

Devices that treat a condition that affects >8,000 USA patients per year.

→ Humanitarian Device Exemption

Is the device low to moderate risk of harm to the patient/user?

- Would the product be intended to inform/aid in diagnosis?
- Would it be installed on the body for between 24 hours and 30 days?
- Are general controls insufficient to assure the safety and effectiveness of the device?

Is the device high risk of harm to the patient/user?

- Would it come into extended contact with the body (greater than 30 days)?
- Could it present a potential unreasonable risk of illness or injury?
- Is there insufficient evidence to provide reasonable assurance of the safety and effectiveness of the device?

Is the product a pre-amendment device, or has it been specifically exempt from 510(k) from the FDA?

Is there a similar product on the market, which has already been cleared by the FDA, that you can demonstrate substantial equivalence to?

Is the product a pre-amendment device, or has it been specifically exempt from 510(k) from the FDA?

De Novo Classification:

A novel device that would automatically be classified as Class III can apply for De Novo classification in order to automatically reclassify as Class I or II.

Class I 510(k) Exempt ~45%	Class I Non-Exempt ~2%	Class II 510(k) Exempt ~21.5%	Class II Non-Exempt ~21.5%	Class III ~10%
• oxygen mask • ventilator tubing • irrigating syringe • tongue depressor • elastic bandage • hospital bed • etc.	• anti-microbial medical glove • medical adhesive tape • etc.	• acupuncture needle (single use) • pediatric medical crib • clinical mercury thermometer • daily contact lenses • etc.	• catheter • sharps container • neonatal incubator • hypodermic needle • blood pressure alarm • etc.	• atrial defibrillator • implanted pacemaker • breast implants • anything permanently implanted • etc. Other device examples can be found on https://www.fda.gov/ under “Device Panels.”
General Controls		*Special Controls*	*Clinical Data*	

IDE - Investigational Device Exemption https://www.fda.gov/

Only needed in some cases, IDE “ allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.”

If the device trips the exemption for any reason, even if it was originally exempt, the device may still be required to submit 510(k).

510(k) Exempt

“A device may be exempt from 510(k) requirements if the FDA determines that a 510(k) is not required to provide reasonable assurance of safety and effectiveness for the device.” https://www.fda.gov/

Premarket Notification (510(k))

“...must demonstrate to FDA’s satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market” https://www.fda.gov/

Premarket Approval (PMA)

“...any new products that contain new materials or differ in design from products already on the market. A PMA submission must provide valid scientific evidence collected from human clinical trials showing the device is safe and effective for its intended use” https://www.fda.gov/

FDA Registered or Listed

Clearance to Market Device

Approval to Market Device