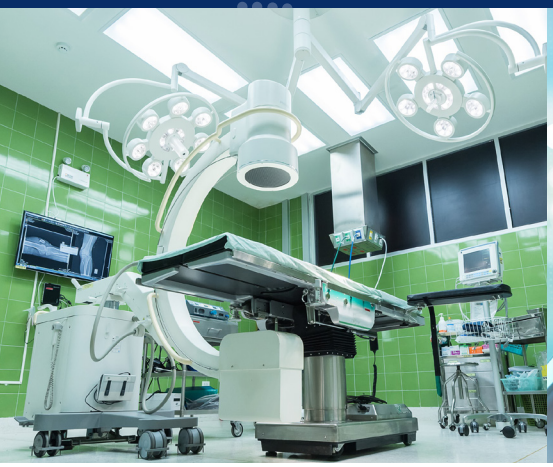
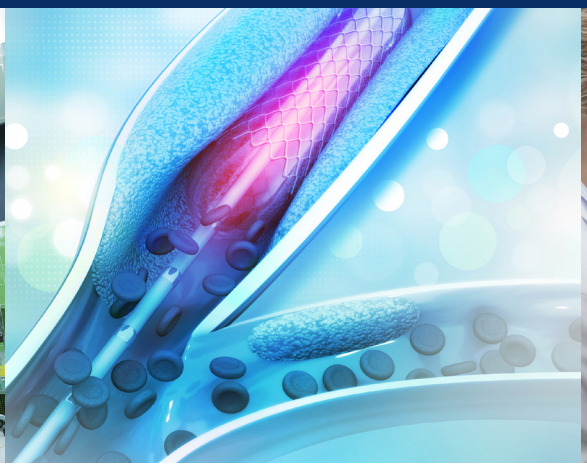
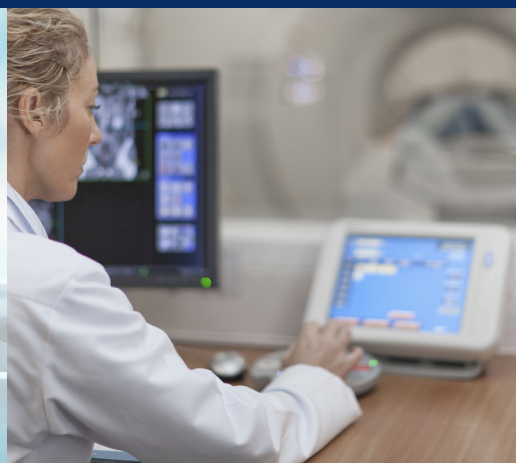
US

How FDA Defines Substantial Equivalence to a Predicate Device

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Predicate Device

The concept of substantial equivalence of medical devices was introduced by the US Food and Drug Administration (FDA) as part of the Medical Devices Amendment (MDA) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) enacted on May 28, 1976.

The MDA gave the FDA authorization to issue regulations classifying all medical devices into three classes, based on the level of controls they deemed necessary to provide reasonable assurance of their safety and effectiveness. As such, the following three device classes were defined:

Class I (Low Risk)	Devices are subject to general controls that are applicable to all classes of devices.
Class II (Medium Risk)	Devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and are therefore subject to special controls to provide such assurance.
Class III (High Risk)	Devices for which general controls alone are insufficient and for which there is not enough information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require premarket approval (PMA).

What is a Predicate Device?

FDA defines a predicate device as a legally marketed device that:

- was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required; or
- has been reclassified from Class III to Class II or I; or
- has been found substantially equivalent through the 510(k) process.

What is a Premarket Notification and 510(k)?

The term 510(k) is a notification to the FDA that should occur at least 90 days prior to introducing a device, intended for human use, to interstate commerce for commercial distribution, contingent upon certain requirements.

This process applies to most Class II as well as some Class I and a few Class III devices. These devices are considered to have a moderate level of risk for which special controls, such as performance standards, post-market surveillance, and labeling requirements, can be applied to obtain a reasonable assurance of safety and effectiveness

Predicate Device

How does FDA define substantial equivalence?

FDA defines a "substantially equivalent" or "substantial equivalence" device that is being compared to a predicate device, as a device that:

- has the same intended use and technological characteristics as the predicate device, or
- has different technological characteristics and the information submitted demonstrate that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device.

How does a device demonstrate substantial equivalence?

The 510(k) paradigm partially relies on the FDA's previous determination that a reasonable assurance of safety and effectiveness exists for the predicate device. Therefore, demonstrating that the new device is substantially equivalent conveys the same reasonable assurance of safety and effectiveness.

The criteria for determining a substantial equivalence between a predicate device and proposed device are:

- The predicate device has the same intended use as the proposed subject device.
- The predicate device and proposed device should be defined by the same FDA regulation number and product code.
- The proposed device has the same technological characteristics as the predicate device. If they differences exist, they should not raise any new questions of safety and effectiveness of the proposed device.

What are the most common reasons for NSE decisions?

The main reasons for a NSE are:

1. **NO PREDICATE** — a suitable predicate does not exist;
2. **NEW INTENDED USE** — the intended use of the new device is different than the intended use of the predicate;
3. **NEW TECHNOLOGY** — the technology is not substantially equivalent to the existing technology for the predicate; and
4. **LACK OF PERFORMANCE DATA** — there were no performance data provided in the 510(k) submission, the data provided were inadequate, or the data failed to demonstrate device performance was at least equivalent to the identified predicate.

Recommend-ations

- Even though, the concept of showing substantial equivalence looks simple, it is very complicated as it involves a good understanding of regulations, guidance documents, and standards, and requires a thorough understanding of the FDA's policies and expectations. Submitting a 510(k) is not a simple administrative task it should occurs once the new device is ready for the market.
- Early consideration of substantial equivalence is recommended to obtain a well-organized, scientifically valid, comprehensive compilation of documents that enables the FDA to determine the new device is substantially equivalent to the predicate device.
- Preparing for marketing clearance via a 510(k) should start during early development of the device so decisions about design, materials, operation, performance specifications, and other technological considerations are well understood with regard to showing substantial equivalence. It needs to continue during the verification and validation activities to ensure adequate and appropriate data are available.

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REFERENCES

https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.pdf

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