

FDA Services - Frequently Asked Questions

1. What is the FDA Definition of a Medical Device?

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including a component part, or accessory which 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, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of 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 any of its primary intended **purposes**.

2. When is a Product Considered Radiation Emitting?

Definition of Electronic Product Radiation:

A. The term "electronic product radiation" means:

- any ionizing or non-ionizing electromagnetic or particulate radiation, or
- any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

B. The term "electronic product" means:

- any manufactured or assembled product which, when in operation,
 - contains or acts as part of an electronic circuit and
 - emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
- any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

C. The term "manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products.

3. Are Radiation-Emitting Devices Considered Medical Devices?

Most radiation-emitting products are not considered to be medical devices. However, if you make any medical claims, your product is a medical device also subject to the provisions of the

FD&C Act (Federal Food, Drug, and Cosmetic Act) for medical devices in addition to the provisions for radiation emitting products.

4. How Do I Determine the FDA Classification or Exemption Status of my Medical Product?

TÜV SÜD Canada will investigate the classification and the exemption status for your product. With our extended knowledge and background, we will accurately identify the classification and the CDRH requirements for FDA approval. This will ensure that the appropriate paths to compliance are followed from the outset and eliminate any problems during the FDA review. Our goal is to speed your time to market.

5. What if my Product is Exempt?

Some Class I devices are exempt from the premarket notification and/or parts of the good manufacturing practices regulations. Approximately 572 or 74% of the Class I devices are exempt from the premarket notification process. The Food and Drug Administration (FDA) has also published a list of class II (special controls) devices (those devices are annotated as "(II)", subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Global Advantage will provide guidance and assistance in determining exemptions and preparing an exemption report to FDA.

6. What is Required to Prepare and Submit an FDA 510K Report?

TÜV SÜD Canada will provide guidance and assistance in preparing the 510K report to FDA. Section 510(k) of the Food, Drug, and Cosmetic Act requires those device manufacturers who must register to notify FDA at least 90 days in advance of their intent to market a medical device. This is known as Pre-Market Notification also called PMN or 510(k). It allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified.

Specifically, medical device manufacturers are required to submit a Pre-Market Notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

7. What is a Pre-Amendment Device?

For Class III devices, a Pre-Market Approval Application (PMA) will be required unless your device is a pre-amendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMAs have not been called for. In that case, a 510k will be the route to market.

8. What if a PMA is Required?

TÜV SÜD Canada will provide guidance and assistance in preparing the PMA (Pre-Market Approval) report to FDA. Pre-Market Approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

An approved Pre-Market Approval Application (PMA) – like an approved New Drug Application (NDA) – is, in effect, a private license granted to the applicant for marketing a particular medical device. A Class III device that fails to meet PMA requirements is considered to be adulterated under Section 501(f) of the act and cannot be marketed. Pre-Market Approval requirements apply differently to pre-amendments devices, post-amendments devices, and transitional Class III devices.