Ankin Law Office LLC
Protecting the Rights of Injured Workers

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510(k) Premarket Clearance Requirements for Medical Devices

When a manufacturer wishes to introduce a new **medical device** or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected, the manufacturer must provide the U.S. Food and Drug Administration (FDA) with a Premarket Notification (PMA) in the form of a 510(k) submission at least 90 days in advance of commercial distribution so that the FDA can determine if the device is "substantially equivalent" to a device already placed in one of the FDA's three classification categories. After the 510(k) has been submitted, the manufacturer must receive premarket clearance from the FDA before the device can be commercially distributed.

The requirement that a new device be substantially equivalent to a device that is already legally in commercial distribution is designed to ensure that the new device is at least as **safe and effective** as the predicate device. A device will be considered substantially equivalent if (1) it has the same intended use as the predicate device and the same technological characteristics as the predicate; or (2) it has the same intended use as the predicate and, if it has different technological characteristics, the information provided to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device. The devices do not need to be identical to be considered substantially equivalent.

The Center for Devices and Radiological Health (CDRH) has implemented a Third Party Review Program whereby manufacturers have the option of submitting their 510(k) to private parties that have previously been identified by the FDA for review instead of submitting directly to the CDRH.

Who Must File a 510(k)?

The Federal Food, Drug and Cosmetic Act (Act) requires that the following are subject to the 510(k) premarket notification and clearance requirements:

Domestic manufacturers introducing a new device into a U.S. market;

Specification developers introducing a device to the U.S. market;

Repackers or relabelers who make labeling changes or whose operations significantly affect the device; and

Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

When Must a 510(k) Be Filed?

A 510(k) premarket notification must be submitted to the FDA whenever a manufacturer (1) wishes to introduce a new device into the market for the first time, (2) proposes a different use to a device already in commercial distribution, or (3) plans to change or modify a legally marketed device in such a way that could significantly affect its safety or effectiveness.

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When is a 510(k) Not Required?

"Preamendment devices," or devices legally marketed in the U.S. by a firm before May 28, 1976 that have not been significantly changed or modified and for which a regulation requiring a PMA application has not been published by the FDA, are considered "grandfathered" devices and do not require a 510(k) PMA, provided that the device has the same intended use as when it was originally marketed before May 28, 1976. If the device is labeled for a new intended use, then the device is considered a new device and a 510(k) must be submitted to the FDA

Additionally, a 510(k) submission is not required in the following instances:

The sale of unfinished devices to another firm for further processing or assembly;

The development, evaluation or testing of a device that is not yet commercially distributed;

The distribution of another firm's domestically manufactured device;

The repackaging or relabeling of a device if the existing labeling or condition of the device is not significantly changed and is consistent with the labeling submitted in the 510(k);

The device was legally in commercial distribution before May 28, 1976 and supporting documentation is available;

The importation of a foreign-made device if a 510(k) has been submitted by the foreign manufacturer and clearance was received;

The device is exempted from 510(k) pursuant to Regulation 21 CFR 862-892, which provides that certain Class I or II devices can be marketed for the first time without having to submit a 510(k). A list of the Class I and II exempted devices can be found on the FDA's website.

What Information Must Be Included in a 510(k) Premarket Notification?

Typically, a traditional 510(k) is submitted to the FDA when a manufacturer seeks premarket clearance, although in some cases an abbreviated 510(k) or a specific 510(k) may be submitted. The traditional 510(k) includes the following:

A Medical Device User Fee Cover Sheet;

Certification of compliance with the ClinicalTrials.gov Data Bank;

A cover letter;

A statement/summary of the device's intended use(s);

A 510(k) summary or statement;

A Standards Data Report if a national or international standard is referenced;

A statement of truthfulness and accuracy;

Class III certification and summary for Class III devices; and

Specific information regarding the device including its name, description, comparison to the predicate (including similarities and/or differences), intended use and proposed label, as well as any information on sterilization, biocompatibility and/or expiration date, if applicable.

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By Admin - CO
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