# PUBLICATION

## FDA Issues Kinder, Gentler Medical Device 510(k) Clearance Action Plan

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On January 19, 2011, the Food and Drug Administration (FDA) issued a program intended to streamline and improve the approval process that medical device manufacturers must navigate before they can market and sell their products. The Plan of Action for Implementation of 510(k) and Science Recommendations (Action Plan) seeks to remove barriers in the approval process that stifle innovation in the industry.

Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification. This allows the FDA to determine whether the device is equivalent to a device already classified by the FDA and thus eligible for marketing. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be 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. When the FDA authorizes the marketing of the device, it is referred to as a 510(k) clearance.

The Action Plan identifies 25 changes the FDA Center for Devices and Radiological Health (CDRH) intends to make during 2011 to make the 510(k) processes more efficient. The FDA will establish certain transparency actions such as creating a public database for medical device information dissemination and requiring safety and effectiveness statements from manufacturers for select high-risk medical devices through the case-by-case specific guidance.

According to CDRH Director Jeffrey Shuren, this Action Plan is meant to "increase predictability, reliability and efficiency" of the FDA regulatory pathways for premarket clearance for medical devices. Among the Action Plan items is a proposal for a streamlined "de novo" review process. The FDA also proposes to create a new Center Science Council of senior FDA experts to facilitate the 510(k) program processes and "assure more timely and consistent science based decision making." It also proposes to develop a network of experts to assist the FDA in addressing "important scientific issues regarding new medical device technologies." The Action Plan items are broken down by category and include milestone dates of completion for regulatory guidance, internal and administrative items, programmatic and regulatory changes, and issues that are to be referred to the Institute of Medicine (IOM).

Updates on the status of planned Action Plan items will be posted on the CDRH website. The FDA will provide additional opportunity for industry input and comment on certain matters such as draft guidance and regulations prior to finalization. There may also be CDRH-issued device specific guidance on four issues on a case-by-case basis. They include: "(1) when and what type of manufacturing data to submit; (2) when a pre-clearance inspection would be conducted; (3) when and what types of modifications should be periodically reported in lieu of submitting a 510(k); and (4) when and what type of safety and effectiveness information for the device to be reviewed that is known to the manufacturer should be submitted as a brief description." This issue guidance is not included in the Action Plan since it will be case specific.

For more information about this, please contact one of our Drug, Device & Life Sciences attorneys or your Baker Donelson attorney.