

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

4/17/92

SMDA CHANGES

PREMARKET NOTIFICATION; REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INSERT

Since this booklet was published, Congress has amended the Federal Food, Drug, and Cosmetic (FD&C) Act, in the Safe Medical Devices Act (SMDA) of 1990, which became law on November 28, 1990. This attachment contains a list of the new SMDA provisions which most specifically pertain to Premarket Notification not included elsewhere in this publication. An updated edition of the Premarket Notification Booklet will be issued in the near future. Meanwhile, more information on SMDA can be found in a booklet available from the Division of Small Manufacturers Assistance, "Highlights of the Safe Medical Devices Act of 1990 (Public Law 101-629)."

NEW SMDA PROVISIONS THAT MOST SPECIFICALLY APPLY TO PREMARKET NOTIFICATION

- o As part of the 510(k) submission, the submitter must provide either a summary of any safety and effectiveness information upon which the substantial equivalence is based, or state in the premarket notification that safety and effectiveness information will be made available by the submitter to interested persons upon request. Either a 510(k) summary or this 510(k) statement MUST be included in your premarket notification submission for FDA to complete its review. This requirement affects all devices that are subject to premarket notification.
- o The safety and effectiveness information in the 510(k) summary as mentioned, refers to that information upon which an equivalence determination is based. Depending on the device, this 510(k) summary could be descriptive information about the new and the legally marketed device, and in addition for some devices, about performance or clinical evaluation.
- o Any 510(k) summaries of information about safety and effectiveness of a device shall be made available by FDA upon request by the public within 30 days of a determination of substantial equivalence.
- o The manufacturer must obtain an FDA letter of substantial equivalence determination before beginning commercial distribution of a device for which a premarket notification [501(k)] has been submitted.

- o Substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

- o Manufacturers who claim that their device is substantially equivalent to a Class III preamendments device introduced into interstate commerce before December 1, 1990, and for which a Premarket Approval (PMA) regulation calling for a PMA has not been issued must comply with a Class III summary and certification requirement. They are required to certify that they have conducted a reasonable search of all information known or available about that type of device, and to submit a summary description of the types of safety and effectiveness problems associated with the type of device, the causes of the problems, and a citation to the literature or other sources of information upon which the description is based.

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