Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)

510(k) Memorandum #K86-3

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. June 30, 1986

Premarket Notification Review Program

[NOTE: TWO ATTACHED FLOWCHARTS, "510(K) 'SUBSTANTIAL EQUIVALENCE DECISION-MAKING PROCESS" (OVERVIEW) AND (DETAILED), ARE LOCATED AT THE END OF THIS DOCUMENT]

The attached guidance document on the Center for Devices and Radiological Health's premarket notification review program results from several years of discussions on 510(k) issues, beginning with the work of the Center's Premarket Notification Criticism Task Force. The concepts appearing in the document were developed using the input from ODE Division Directors, Branch Chiefs, reviewers and other staff members. Mr. Villforth, Mr. Scarlett, Mr. Norris and Dr. Young have reviewed the guidance and concur with it. The

GUIDANCE ON THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PREMARKET NOTIFICATION REVIEW PROGRAM

(June 30, 1986)

PURPOSE OF THE GUIDANCE

This guidance document outlines requirements for premarket notification review, and explains some points the Center for Devices and Radiological Health (CDRH) will consider when making a determination that a device is, or is not, "substantially equivalent." A consistent application of the principles set forth in the guidance should be useful to Center staff in conducting complete and expeditious reviews of 510(k) submissions.

PURPOSE OF THE PROGRAM

In brief, the premarket notification program is meant to:

- identify new devices that must be placed automatically into class III and undergo premarket approval or reclassification before they are marketed;
- classify new devices; a not substantially equivalent (NSE) new device is in class III, and a substantially equivalent (SE) new device is in the same regulatory class as the device to which it is found equivalent; and
- achieve marketing equity by allowing manufacturers of new devices that are SE to pre-Amendments devices to market their devices without facing any greater regulatory burdens than faced by manufacturers of the pre-Amendments devices.

BACKGROUND

THE STATUTE: The Medical Device Amendments were enacted on May 28, 1976. They direct FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories, class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that must be met before a manufacturer may distribute the device in interstate commerce.

Class I devices are subject to a comprehensive set of regulatory authorities applicable to all classes of devices, e.g., premarket notification, registration and listing, prohibitions against adulteration and misbranding, and rules for good manufacturing practices. Class II devices also need performance standards, and class III devices need premarket approval.

The Act also specifies how a new device, i.e., a post-Amendments device, is to be classified. A post-Amendments device is automatically in class III and must undergo premarket approval or reclassification before it can be marketed, unless it is a type of device that was in commercial distribution prior to May 28, 1976 and is SE to another device within such type; or, it is within a type of device introduced after May 28, 1976 that has been reclassified into class I or II and is SE to another device within such type. A SE device is in the same class, and is subject to the same requirements, as the device to which it is SE.

Section 510(k) of the Act requires a person who wishes to introduce a device into commerce to notify the Center at least ninety days in advance. This premarket notification is referred to as a "510(k)." The Agency uses 510(k)s to determine if new devices are, or are not, SE to either a pre-Amendments device or a reclassified post-Amendments device.

CONGRESSIONAL GUIDANCE: The statutory objectives for the 510(k) program are clear. Also, the Report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 (House Report) offers some additional guidance on program implementation, describing the term "substantial equivalence" as follows:

> The term "substantially equivalent" is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between "new" and marketed devices in materials, design, or energy source, for example, would have a baring on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.1/

If substantial equivalence were judged too narrowly, the marketing of devices that would benefit the public would be delayed; the device industry would be unnecessarily exposed to the greater burdens of premarket approval; new devices would not be properly classified; and new manufacturers of pre-Amendments type