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.

GUIDANCE DOCUMENT FOR THE PREPARATION OF PREMARKET NOTIFICATION [510(K)] APPLICATIONS FOR HEATING AND COOLING DEVICES

July 26, 1995
(reformatted 12/18/97)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the Restorative Devices Branch at 301-594-1296.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

PREFACE

The purpose of this document is to provide guidance to the sponsors of premarket notifications [510(k)'s] for restorative devices. This document is intended to assist the sponsors in organizing and providing the essential information that should be submitted to the Food and Drug Administration (FDA) for review.

This guidance is based on the Restorative Devices Branch's (REDB's) identification of specific criteria necessary to conduct an adequate evaluation of a 510(k) for the purpose of determining substantial equivalence for physical medicine/restorative devices. The objective of this document is to delineate to the device manufacturer important administrative, descriptive, and scientific information that should be included in a 510(k) for a restorative device. Individual 510(k) submissions may require additional information pertinent to each specific device. The suggestions and recommendations included in the guidance reflect the minimal requirements that would allow an evaluation of the device as determined by REDB. While the use of this document in the preparation of a 510(k) premarket notification will not ensure FDA clearance of a device, following the guidance will ensure that sufficient basic information is available to initiate a substantive review.

Note that the guidance document is a living document. It will be periodically revised as scientific knowledge and regulations change.

INTRODUCTION

Any 510(k) notification submitted under premarket notification procedures described in 21 Code of Federal Regulations (CFR) Part 807, Subpart E, for FDA's determination that a new device is substantially equivalent to a predicate (existing) device in 21 CFR 890.5950 (Powered Heating Unit), 21 CFR 890.5740 (Powered Heating Pad), 21 CFR 890.5500 (Infrared Lamp), 21 CFR 890.5720 (Water Circulating Hot or Cold Pack), or Class I by 21 CFR 890.5710 (Chemical Hot/Cold Pack) should follow the format below and must contain all specified information that is pertinent to the device.

ADMINISTRATIVE INFORMATION

1. Provide the name and address of the manufacturer and sponsor of the 510(k) submission.

2. Provide the FDA registration number (if available) of the manufacturer of the new device.

3. Identify the official contact person for all correspondence.

DEVICE IDENTIFICATION

1. As stated in 21 CFR 807.90(d), a 510(k) shall be submitted separately for each product the manufacturer intends to market. Therefore, a submission can describe no more than one new device.

   A submission can describe more than one component of, or attachment to, a single device. The submission must compare each such component or attachment with that of a predicate device, or must state that the predicate device lacks such a component or attachment.

2. The following information must be provided:

   a. The proprietary name of the new device;

   b. The generic name of the device;

   c. The classification of the predicate device e.g., Class II. Refer to 21 CFR and section 513 of the Food, Drug, and Cosmetic Act;

   d. The proposed regulatory class for the new device, e.g., Class II. (21 CFR 862-892 contains the regulatory classifications for medical devices); and

   e. The panel code(s) for the device. [If the product is not classified under the physical medicine devices panel, identify the panel under which it is classified and provide the panel identification code (e.g., 89 is the code for the physical medicine devices panel)].

3. Specify whether this device:

   a. Has been previously submitted to the FDA for identical or different indications;

   b. Is currently being reviewed for different indications by the same or different branch within ODE; or

   c. Has been previously cleared by the FDA for different indications.

DEVICE DESCRIPTIVE INFORMATION

Intended Use

Identify the specific intended use(s), including the specific therapeutic indications, for the subject device and the predicate device. The new device must have the same intended medical uses as those specified for the predicate device, to the extent that the changes do not alter the therapeutic or diagnostic effect and do not affect the safety and effectiveness. These intended uses must be consistent with the descriptions of intended medical uses contained within the CFR section that is applicable to the device and must identify the specific medical conditions for which the device is indicated. If the indication differs, you must provide a justification as to how the change(s) do not affect safety and effectiveness. If special labeling claims are sought, information must be provided to support these claims.

It is not necessary to notify FDA of an intent to market a device if it will not be labeled or promoted for medical uses. However, FDA will regulate the equipment and may require premarket notification if any promotional material appears which makes medical claims after marketing begins.

Device Description

1. Provide a written description of the device, including all device components, instruments, and any new features of the device.

2. Identify all sizes, configurations, and functions of each device component.

3. Describe how the device works and interconnects with other components.

4. Engineering drawings and/or photographs and complete written descriptions of the new and predicate devices. The document must contain illustrations of all internal and external features of both devices. Engineering drawings must provide the lengths, widths, and heights of the devices and their major component parts.

6. Provide the temperature range of the device.

7. Provide the temperature range at the skin surface where device is applied.

Materials

Identify the specific materials for each component, any additional processing that may affect the material properties, and the voluntary standards with which the device materials will conform.
In the case of powered heating pads, the material of the heating pad cover must be specified. Similarly, the chemicals and activator(s) used in hot/cold packs must be described.

Labeling

1. Provide draft or sample package labeling, package inserts, including complete operator's instructions for the new device.

2. Include copies of promotional materials for the new and predicate devices.

3. The following warning statement must be included in the labeling for all devices:

> "WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of ..... by children or incapacitated persons may be dangerous."

Additional Information

1. The distance of the device from the area of application must be provided for infrared lamps.

2. The leakage current must be specified for powered heating pads, infrared lamps, and water circulating hot/cold packs.

3. The flow rate, pressure, and the liquid to be used must be specified for water circulating hot/cold packs.

SUBSTANTIAL EQUIVALENCE INFORMATION

1. The legally marketed predicate device with which the subject device is to be compared for the determination of substantial equivalence must be identified. Evidence must be provided that the device was placed into interstate commerce for other than research uses or as part of a plant-to-plant transfer and was actually labeled and promoted for the intended use to which the submitter of the premarket notification is claiming substantial equivalence. This may be accomplished by providing copies of the firm's advertisements, catalog pages, or other promotional material dated prior to May 28, 1976 and shipping documents such as invoices, bills of lading, receipts showing the interstate transit of the device (for other information which can be used to prove Pre-Amendment status contact DSMA).

   Alternatively, the 510(k) number(s) of the predicate device(s) may be identified. The 510(k) number may be obtained from the Electronic Docket (ED), an automated retrieval system of the Division of Small Manufacturers Assistance (DSMA), which provides medical device regulations, FDA talk papers and press releases, device evaluation guidance,

and the listing of all approved 510(k)s sorted by applicant name. This 510(k) information is located under the Product Clearance Main Menu Item # 12. Dial (301) 594-4802 or (800) 252-1366. For more guidance on how to assess this information, contact DSMA. Call toll free (800) 638-2041, (301) 443-6597, or fax (301) 443-8818.

2. The submission should include a description of all significant similarities and differences between the new and predicate device. To facilitate the review, the submission should contain a table which compares the intended medical uses and the physical characteristics and functions of the two devices.

510(K) SUMMARY OR STATEMENT

1. Provide a 510(k) summary of safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based, written in accordance with the content and format requirements that are specified in 21 CFR 807.92

or

2. Provide a 510(k) statement that safety and effectiveness information will be made available to interested persons upon request. This statement must follow the format and contain the wording as specified in 21 CFR 807.93.

TRUTHFUL AND ACCURATE STATEMENT

Provide a statement that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted, as required by 21 CFR 807.87(j).