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BIOFEEDBACK DEVICES
DRAFT GUIDANCE FOR 510(K) CONTENT

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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 General Surgical Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the General Surgical Devices Branch at 301- 594-1307.**
- **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
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INTRODUCTION

This document is to be used in conjunction with the Division of Cardiovascular, Respiratory and Neurological Devices "Draft Guidance for Format and Content for Premarket Notification 510(k)", which provides guidance for preparing a "510(k)" premarket notification. This "Guidance for Biofeedback 510(k) Content" provides more specific guidance for 510(k)s that claim equivalence to biofeedback devices.

I. BASIC DESIGN DESCRIPTION

The file should include a complete and precise description of the device which includes a description of the functional characteristics, the controls, and all feedback and other data provided to the user. This must be accompanied by copies of all feedback displays, and pictures or drawings of the device. The intended use must be clearly stated and must be consistent with the "indications" specified in the product labeling.

II. COMPARATIVE DEVICE SPECIFICATIONS

The manufacturer (or importer) is to provide a discussion indicating the similarity and/or difference of the device to legally marketed comparable products which are used for biofeedback, accompanied by data to support the statement. This should include an identification of similar products, design considerations, energy delivered by the device, and a description of the operation principles of the device. The firm that intends to market the device must be specific as to the similarities and differences in regard to the device to which it is being compared. The comparison must include the physiological parameters being monitored, the feedback and data provided to the user, the intended use and any other feature which could impact on safety or effectiveness. Pictures, drawings, and labeling, sufficient to describe the similarities and differences between the devices are to be included. If the predicate device was the subject of any prior premarket notifications, file numbers for those documents should be specified to facilitate the review.

A. Transducers

The file must describe in detail all transducers associated with the device. Performance specifications should be compared with those of the predicate device. If transducers are not to be provided with the device, the file must identify those that have been tested with the device accompanied by data that assures they are compatible with the device. The instructions for use (See V. LABELING) should identify those marketed transducers that are compatible with the device.

B. Feedback Modes

All feedback modes and output data provided by the device must be completely described. This should include a discussion that explains the relevancy of any data provided for biofeedback to the intended use. Copies of all feedback displays produced by the device must be included in the file, along with the numeric range, units of measurement and increments for all feedback displays.

C. Electrical Safety

1. If the device is line-powered, the file must describe the design features that assure the patient will be isolated from AC line voltage under any condition of electrical component failure. This should take into consideration the effect of any line-powered accessories that connect to the device, and the use of a line-powered

battery charger if the device is powered by a low voltage battery. All testing performed to assure patient safety should be described and explained.

2. The electrical connection between the device and the patient leads must be described in detail. If connectors are used, there must be an explanation of the method used to preclude accidental connection to a dangerous power source, e.g. an AC power outlet. (See reference 3.)

D. Electrodes and Conductive Media

The electrodes and conductive media to be used with the device must be completely described. This description should include the composition of all materials used these components, the results of testing conducted on the material that assures that the material does not present a risk of skin irritation or toxic effect on the patient, and the dimensions of the electrodes. If the firm submitting the premarket notification does not manufacture these components, they must identify the manufacturer and trade names of these components. If the electrodes and conductive media supplied with the device have been the subject of a previous premarket notification the file number for the premarket notification should be provided to expedite review.

E. Intentional Electrical Current

If the device is used to measure the electrical resistance of the skin (or conductance), an accurate specification of the electrical signal employed by the device to measure skin resistance must be provided. The waveshape and the maximum amplitude of the signal must be clearly specified.

F. Risk of Thermal Injury

If the device directs light energy such as infrared on to the skin, an explanation must be provided, accompanied with data, that assures that the energy will not present cause injury to the subjects skin. Temperature measurements of the skin surface exposed to the energy are desirable. A discussion of any safety features included in the circuitry of the device to limit the amount of current driving the energy transducer must be included.

III. INDUSTRY STANDARDS

The manufacturer must indicate the extent to which the device conforms to any industry standard (i.e., UL544, or any other electrical safety standard).

IV. TEST DATA

The manufacturer must provide performance data demonstrating that the device performs as safely and as effectively as a legally marketed predicate device, and that it meets the design requirements. This data can be obtained from bench testing or "in vitro" testing performed on the device. Data should include the protocol for the testing, the pass-fail criteria, and the test results. A summary explanation of how the testing demonstrates that the design requirements are satisfied and how the design requirements are related to device performance should also be included.

A. Environmental Testing

A discussion should be included explaining the assurances the manufacturer has that the device will perform reliably in the environment in which it is intended to be used. The discussion should include any data from environmental testing that has been performed, and an analysis of that data. Identification of testing equipment and procedures should be included in the discussion.

B. Software

For devices that employ a microprocessor or other software-controlled component, the type of information needed in the file is specified in the Reviewer Guidance Document for Computer Controlled Medical Devices (See Ref. 6.) The file must include a hazard analysis and must specify the level of concern as described in Chapter 2 of Reference 6. As discussed in the reference, the software information is to be provided with a level of detail consistent with the level of concern.

V. LABELING

The file must include copies of all proposed label, labeling, and advertisements. If this material has not been developed, drafts of the text must be provided which are sufficient to describe the intended use for which the device will be promoted and to provide adequate directions for use.

Biofeedback devices to be promoted for indications other than relaxation require prescription legend pursuant to Title 21, Code of Federal Regulations, Section 801.109 (21 CFR 801.109) (enclosed). Lack of a prescription legend can affect classification.

A. Indications

Pre-Amendment biofeedback devices were used for relaxation training and muscle re-education. Any other intended use must be supported by valid scientific data. Documentation must describe clinical studies that utilized the subject device, the results of the study, and analysis that supports the claim of effectiveness. If a new use raises new scientific issues, then the device is a new device, i.e., it is not equivalent to preamendment biofeedback devices.

B. Instructions for Use

The instructions for use must explain how the device is to be used to accomplish its intended use and must explain the purpose and function of all accessories, displays, data, and connectors the device and how they are used. These instructions must identify all transducers to which the device is to be connected and must instruct the user how to use the device, once the connections have been made.

REFERENCES

1. "Connection of Electrode Lead Wires to Line Power", Health Devices, Emergency Care Research Institute, pp.44-46, Feb. 1987.

2. "Risk of Electric Shock from Patient Monitoring Cables and Electrode Lead Wires", Health Devices, Emergency Care Research Institute, pp.301-303.

3. "FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices", December 28, 1993.

4. American National Standard, Safe Current Limits for Electromedical Apparatus ANSI/AAMI ES1 1985. Association for the Advancement of Medical Instrumentation, 1901 North Fort Meyer Drive, Suite 602, Arlington, Virginia 22209.

5. Standard for Medical and Dental Equipment--UL 544, Second Edition 1976, (Reprinted May 21, 1992), Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook, Illinois 60062.

6. "Reviewer Guidance for Computer Controlled Medical Devices", Center for Devices and Radiological Health, August 29, 1991.