

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 SUBMERGED (UNDERWATER) EXERCISE EQUIPMENT

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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 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
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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, should follow the format below and must contain all specified information that is pertinent to the device.

Submerged exercise equipment intended for medical purposes (i.e., to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and as a setting for removal of contaminated tissue), are in the same classification as hydrobaths (21 CFR 890.5100; Class II). However, if such claims are not made, submerged exercise equipment may be considered either non-measuring exercise equipment (21 CFR 890.5370; Class I) or powered exercise equipment (21 CFR 890.5380; Class II).

ADMINISTRATIVE INFORMATION

1. Provide the name, address, phone and fax number 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.
4. Identify whether confidentiality is requested. Requests for confidentiality must contain all information specified in 21 CFR 807.95(b).

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 (trade) name of the new device;
 - b. The generic (common or usual) 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, i.e., Class II (performance standards). (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)]. See HHS Publication Number FDA 91-4246 (Classification Names for Medical Devices and In Vitro Diagnostic Products) for guidance.
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 diagnostic and/or 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 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.

Identify all available and intended motions, and the muscles and/or joints to be exercised. These intended uses should be clearly identified in the labeling.

Note that FDA regulates exercise equipment only if the equipment is intended to be used for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. FDA does not regulate exercise equipment intended only for general physical conditioning and/or for the development of athletic abilities in individuals who lack physical impairment. Therefore, 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 device description (e.g., mechanical, electrical, materials considerations), specifically including any measuring systems/components, describing how they interface the device, and any new features of the device.

2. Identify the relevant dimensions of the device and all possible configurations.
3. Also, identify all exercise functions, and if applicable, all measuring functions of the new device.
4. Provide engineering drawings and/or photographs of the device, and provide circuit diagrams for novel or complex electrical components or systems. Also provide illustrations or photographs and written descriptions of the predicate device.
5. Provide a hazards analysis for the new device, identifying the device's safety features.
6. For each intended motion, the range of motion through which the intended muscles and/or joints are exercised and the range of forces exerted should be provided. For powered exercise equipment, the speed by which the intended muscles and or joints will be exercised should also be provided.

If available, provide this information for the predicate device (for documentation of substantial equivalence as discussed in Substantial Equivalence section below).

Performance data must be provided for all clinical measuring functions. The testing methodology and conclusions of the testing should be described.

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.

Labeling

1. Provide draft or sample package labeling, package inserts, including complete operator's and maintenance instructions for the new device.
2. Include copies of promotional materials for the new and predicate devices.
3. Depending on the device's indication, the following prescription statement may be required (both on the device itself and in the operator's manual, and in any advertising and/or promotional materials) according to 21 CFR 801.109:

"Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices."

Additional Information

1. If your device uses controlling software, you should refer to the FDA document entitled "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review", dated August 29, 1991. As described in this document, you should determine and justify the level of concern you believe to be associated with your device's software. Further, in accordance with this guidance, provide documentation, commensurate with the level of concern, including: 1) System and Software Requirements & Design, 2) Software

Development, 3) Verification & Validation (V&V), 4) Test Results and Analysis, and 5) Certification. You must also provide a hazards analysis for the software, identifying safety requirements for the software and system.

Please be advised that if you provide only the minimum information highlighted in the "510(k) Review Software Documentation Matrix", this may not assure adequate information to make a determination about the software. In documenting V&V procedures (all levels of concern), you should provide pass/fail and test completion criteria, and a system level functional test plan. You should refer to the sample questions provided in this guidance and to other sources, as necessary. You are encouraged to submit a summary of the development life cycle in terms of how it assures traceability of the safety concerns throughout development, and how the testing and analyses adequately demonstrate that the software meets its functional and safety requirements. Overall, the software documentation provided should allow for an adequate assessment of the quality of the software design and development, and of the level of software quality control.

Copies of this guidance document can be obtained from the Division of Small Manufacturers Assistance (DSMA), at 800-638-2041.

2. Provide the following sterilization and/or disinfection information (as applicable):
 - a. a description of the water filtration system and instructions for its maintenance which include information on how often the filter(s) are to be changed;
 - b. a description of the water treatment system which includes the chemicals to be added and the specifications for the levels of chemicals and pH to be maintained as well as justification for these levels;
 - c. instructions for disinfection of the submerged exercise system which include:
 - 1) the names of all recommended disinfectants;
 - 2) a cleaning step for removal of visible residues or contaminated fluids before disinfection;
 - 3) recommended contact times and concentrations of the disinfectants to be used based on the disinfectants' labels;
 - 4) a rinse step to reduce the residues of the disinfectant remaining on the bath to a nontoxic level; and
 - 5) an examination step after disinfection to check the device for damage and the extent of disinfection; and
 - d. information concerning compatibility of the submerged exercise device materials with the recommended disinfectants.
3. Provide a specification and test reference of the ground leakage current of the new device if it contains electrical components. Note that the ground leakage current must be less than 100 microamperes.

4. For powered exercise devices, a photograph or illustration should be provided clearly identifying the location of the device's safety switch by which the user can stop the operation of the new device. Discuss/illustrate how the safety switch will be identified and easily accessible to the user.
5. Specify all potentially flammable materials used with the new device and whether these materials have been tested in conformance with some standard (specify) or provide the results of testing of the fire-retarding properties of these materials.
6. Provide a statement as to whether the device meets any applicable electrical or mechanical safety standards.
7. Electromagnetic compatibility (EMC):

You should be aware that the issue of EMC may need to be addressed in future applications for this type of device. Such a requirement will be announced in advance.

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 devices. To facilitate review, the submission should contain a summary table which compares the two devices in terms of the intended medical uses, functions and physical characteristics, including safety characteristics. In addition, the submission should provide a written summary as to the substantial equivalence of the new device compared to the predicate in terms of safety and effectiveness considerations.

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).