Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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Table of Contents

Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

Introduction

Among other requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, ultrasonic diathermy devices, also known as ultrasonic therapy or physiotherapy products, must comply with 21 CFR Part 1010 and 1050.10. This draft guidance document describes FDA's recommendations for the performance standard requirements in 21 CFR 1050.10 particular to ultrasonic diathermy devices when a manufacturer has otherwise complied with certain International Electrotechnical Commission (IEC) standards. Because conformance to certain IEC standards identified in this draft guidance adequately addresses the technical concerns intended to be addressed by the performance standard requirements of 21 CFR 1050.10, FDA does not intend to consider whether firms that provide a declaration of conformity and indicate conformance to applicable IEC standards also comply with 21 CFR 1050.10.

In addition, this draft guidance document also provides recommendations for information to provide in 510(k) submissions for these ultrasonic diathermy devices.

For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Background

Ultrasonic therapy devices are both medical devices, under section 201(h) of the FD&C Act, and electronic products, under section 531(2) of the FD&C Act. Ultrasonic therapy devices must comply with radiation safety performance standards in 21 CFR Parts 1010 (Performance standards for electronic products: general) and 1050.10 (Ultrasonic Therapy Products), as required by section 534 of the FD&C Act (a subsection of subchapter C Electronic Product Radiation Control (EPRC)).

FDA recognizes that there are a number of consensus standards from the IEC with which other countries require conformance or recognize. In particular, a number of countries, including the United States (U.S.), recognize the following IEC standards: IEC 60601-2-5: *Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment* and IEC 61689: *Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz* (2013). This means that manufacturers distributing products in both the U.S. and these other countries might have to ensure conformance of their products with IEC standards as well as comply with FDA regulatory requirements. Complying with FDA regulations and conforming to the identified IEC standards can cause manufacturers to duplicate their efforts.

FDA acknowledges the advantages of a universal set of device-specific criteria and requirements and believes that conformance with certain IEC standards would provide at least the same level of protection of the public health and safety from electronic product radiation as the FDA performance standards for ultrasonic therapy products. Therefore, FDA does not intend to consider whether firms comply with certain requirements of 21 CFR 1050.10 if firms provide a declaration of conformity under section 514(c) of the FD&C Act to the relevant provisions of the currently FDA-recognized versions of the IEC 60601-2-5 and IEC 61689 standards. Further description of the declaration of conformity for IEC 60601-2-5 and IEC 61689 is in Section IV of this document. Submitting such a declaration or conformity does not negate other requirements under the FD&C Act and its implementing regulations, including submission of a 510(k). Recommendations regarding the device-specific content of a 510(k) submission are located in Section V of this document.

Scope

The scope of this document is limited to ultrasonic diathermy products regulated under 21 CFR 890.5300(a), product codes IMI and PFW, and are class II devices.

This draft guidance is applicable to ultrasonic diathermy (physiotherapy) devices for use in applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms, and joint contractures. This guidance only relates to equipment employing ultrasonic energy at a frequency beyond 20 kilohertz using a single plane circular transducer per treatment head producing non-convergent beams perpendicular to the face of the treatment head (i.e., collimated or divergent).

Other medical devices that include the use of ultrasound are regulated outside of 21 CFR 890.5300(a) and are excluded from the scope of this guidance. Excluded medical devices include, but are not limited to:

- devices in which ultrasound waves are intended to destroy conglomerates (for example stones in the kidneys or the bladder) or tissue of any type;
- devices in which a tool is driven by ultrasound (for example surgical scalpels, phacoemulsifiers, dental scalers or intracorporeal lithotripters);
- devices in which ultrasound waves are intended to sensitize tissue to further therapies (for example radiation or chemotherapy);
- devices in which ultrasound waves are intended to treat cancerous (i.e., malignant) or pre-cancerous tissue, or benign masses, such as High Intensity Focused Ultrasound (HIFU) or High Intensity Therapeutic Ultrasound (HITU); and
- devices in which ultrasound is intended for aesthetic purposes.

Policy Clarification on Compliance with 21 CFR 1050.10

Submitting a declaration of conformity to the IEC ultrasound physiotherapy standards (IEC 60601-2-5 and IEC 61689) under section 514(c) of the FD&C Act meets most of the requirements in 21 CFR 1050.10 and provides at least the same level of protection of the public health and safety as compliance with 21 CFR 1050.10. Thus, FDA does not intend to confirm compliance with the requirement to demonstrate compliance with the performance standards for ultrasonic diathermy devices in 21 CFR 1050.10, as long as you do not attempt to conform to aspects of both the IEC ultrasound physiotherapy standards and the performance standards in 21 CFR 1050.10. In either case, the information listed in Section V should be provided in a premarket submission.

Manufacturers of ultrasonic diathermy products for which an applicable EPRC performance standard is in effect, including those that conform to applicable IEC standards to meet EPRC performance standards, must provide certifications for their products (see 21 CFR 1010.2(a)). To properly certify their product, manufacturers must furnish product certifications to dealers or distributors, at the time of delivery, that the product conforms to applicable standards in Chapter J (Radiological Health) of Title 21 of the CFR (see 21 CFR 1010.2(a)).

The certification must be provided on a label or tag permanently affixed to or inscribed on the product so as to be legible, readily accessible to view when the product is fully assembled for use, and the label or tag must be in the English language (see 21 CFR 1010.2(b)). FDA does not intend to confirm compliance with 21 CFR 1010.2 for manufacturers that conform to IEC 60601-2-5 and IEC 61689, and who use the following statement on the certification label or tag:

> "Complies with 21 CFR Subchapter J, except for conformance with IEC 60601-2-5 and IEC 61689 instead of the performance standards in 21 CFR 1050.10. See for more information FDA's guidance 'Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices,' dated August 31, 2017."

Under 21 CFR 1010.2(c), this certification must be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program that is in accordance with good manufacturing practice. The manufacturer's quality system should address various aspects of radiation safety and conformity to standards through design controls. Testing results should be documented and placed in the firm's records.

In addition, FDA does not intend to enforce requirements for product reports, supplemental reports, and annual reports as specified in 21 CFR 1002.1 and 21 CFR 1002.2 for these devices for ultrasonic therapy devices cleared for marketing.

510(k) Submission Recommendations

A. Device Description

Per 21 CFR 890.5300, an ultrasonic diathermy device for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. Ultrasonic diathermy devices for therapy produce high-frequency sound waves that travel deep into tissue and create mild therapeutic heat. Generally, therapeutic deep heat is generated if a sustained temperature increase to 41°C – 45°C is achieved.[1] The sound waves are transmitted through a treatment head that the therapist applies to the skin with gentle, circular movements in most cases. A hypoallergenic gel aids in the transmission of the ultrasonic energy. This gel, along with continuous movement of non-stationary applicators, mitigates overheating at the skin surface.

There are three general beam types for ultrasonic devices: **convergent** (or focusing), **collimated**, and **divergent**. The treatment head of an ultrasonic diathermy device should produce a beam that is either collimated or divergent. Please see Appendix A for these and other definitions of terms used in this guidance. Also, for additional relevant definitions, please see the currently FDA-recognized versions of IEC 61689 and IEC 60601-2-5.

[1] Guy, A.W., J.F. Lehmann, and J.B. Stonebridge, *Therapeutic applications of electromagnetic power.* Proceedings of the IEEE, 1974. 62(1): p. 55-75.

You should provide a general description of the subject device in your 510(k) submission, including (but not limited to) model designation, design, patient contact materials, and control panel and system operation. For those who submit a declaration of conformity to the IEC standards, the following information should be included (as applicable) in your 510(k) submission. The following information is based on the IEC consensus standards definitions and terminology. If you choose to comply with the FDA performance standard in 21 CFR 1050.10, you should provide similar information to what is described below, but follow the definitions and terminology found in that performance standard.

- Quantitative indicators should be included for the output power and effective intensity in continuous wave mode of operation and temporal-maximum intensity and temporal-maximum output power in amplitude-modulated mode. The output power indication should not differ from the actual value by more than ±20% of the actual value.

- Generator labeling should include a unique serial number, the acoustic working frequencies, and waveform type (continuous or amplitude modulated (pulsed)). If the amplitude is modulated or pulsed, the generator labeling also should include a description or picture of the output waveform, along with values for the pulse duration, pulse repetition period, and duty factor. If multiple modulation settings are possible, then the description or picture should be for the minimum duty factor.
- Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the treatment head should be provided. This can include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one ultrasonic transducer, they are intended to operate simultaneously and their positions are not fixed relative to each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic transducers with regard to safe use.
- Generators that operate in the pulsed mode and have controls to vary the pulse width and/or pulse repetition period should provide the user with an indication of the magnitude of these quantities. This indication could be provided by a meter or by markings on the control itself.
- Generators for which the ultrasonic frequency is variable should provide the user with an indication of the frequency being used at the time of treatment.
- Treatment head labeling should include its rated output power, the effective radiating area, the beam non-uniformity ratio, the beam type, a unique serial number, acoustic working frequency, and a designation of the specific generator for which the treatment head is intended. If a treatment head has been designed for interchangeability such that it is not possible to specify a particular generator unit, this should be stated and the method by which interchangeability is achieved should be described.
- An adjustable timer that de-energizes the output after a preselected operating period should be incorporated into the device. The timer should have a range not exceeding 30 min and an accuracy of better than ±10% of setting.

- The spatial-peak temporal-average intensity of unwanted ultrasound radiation from a treatment head intended for hand-held use should be less than 100 mW/cm^2 when measured as described in IEC 60601-2-5.
- Any unique features or technological characteristics of the subject device should be described, including for example, but not limited to, descriptions of the types of applicators (e.g. hand-held applicators, stationary applicators enabling hands-free operation, etc.), multiple modes or frequencies.
- Adequate description of the possible range of temperature rise should be provided for a fixed applicator with, if relevant to the device, an explanation that moving the applicator could lower spatial peak temperatures (hot spots) and raise spatial minimum temperatures (cold spots).
- A description (or picture) of the ultrasound field(s) should be provided.

B. Predicate Comparison

Per 21 CFR 807.87(f), the 510(k) must include a comparison of the proposed device to a legally marketed predicate device and provide information to show how the proposed device is similar to and different from the predicate. Predicate 510(k) numbers and side-by-side comparisons, whenever possible, are desirable; for example, using a tabular format as shown below. This type of information should be provided for each treatment head and each acoustic working frequency available. In addition, you should identify and compare any accessories intended for use with the device.

Description	**Subject Device**	**Predicate Device**
Indications for Use		
Manufacturer		
Console/Generator Dimensions (L x W x H cm)		
Treatment Head Dimensions (L x W x H cm)		
Console/Generator Weight (kg)		
Treatment Head Weight (kg)		
Power Supply		
Leakage Current		
Crystal Material		
Technology of ultrasound generation (e.g., piezoelectric, magnetostrictive)		
Treatment Mode(s)		
Beam Type (collimated or divergent)		
Transducer Diameter (cm)		
Acoustic Working Frequency and Accuracy (MHz)		
Effective Radiating Area and Accuracy (cm^2)		
Beam Nonuniformity Ratio (not to exceed 8*)		

Description	Subject Device	Predicate Device
and Accuracy		
Output Mode: (Continuous Wave/Amplitude – Modulated Wave)		
Maximum Timer Setting and Accuracy (not to exceed 30 min*)		
Beam Maximum Intensity and Accuracy (W/cm^2)		
Maximum Values of the following Powers and Intensities (max settings)		
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)		
Maximum Value of the Effective Intensity and Accuracy (Not to exceed 3 W/cm^2 *)		
For Amplitude Modulated Waves		
Pulse Duration and Accuracy (s)		
Pulse Repetition Period and Accuracy (s)		
Duty Factor and Accuracy (%)		
Maximum Value of the Temporal-Maximum Output Power and Accuracy (W)		
Maximum Value of the Temporal-Maximum Intensity and Accuracy (W/cm^2)		
Ratio of Temporal Maximum Output Power to the Output Power		
Temperature Specifications		
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)		
Maximum Patient Contact Surface Temperature of Treatment Head under Simulated or Actual Use Conditions for all Operating Conditions (Continually operated for maximum treatment time) (deg C)		

* Per the IEC 60601-2-5 standard

C. Software

Software in ultrasonic diathermy devices ensures that appropriate energy is delivered to the patient. Adequate software performance testing provides assurance that the device is operating as intended and within safe parameters.

Please refer to FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0

89543.htm) for a discussion of the software documentation that you should provide in your submission. The Software Guidance outlines the type of documentation to be provided based on the "level of concern" associated with the device. FDA generally considers the software for ultrasonic diathermy devices to present a "Major" level of concern. You should also refer to FDA's guidance, *General Principles of Software Validation* (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm) for software development practices.

We recommend that you provide a full description of the software/firmware supporting the operation of the subject device following the software guidance, commensurate with the appropriate level of concern. This recommendation applies to original devices as well as to any software/firmware changes made to already-marketed devices. Changes to software must be revalidated and reverified in accordance with 21 CFR 820.30(f), (g), and (i), and documented in the Design History File in accordance with 21 CFR 820.30(j). Some software changes might warrant the submission of a new 510(k). (See 21 CFR 807.81(a)(3)).

If appropriate, you should also provide information on the Cybersecurity aspects of your device. For more information on this topic, please see FDA's guidance *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356190.pdf).

If the device includes off-the-shelf software, you should provide the additional information recommended in the FDA's guidance documents titled *Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf) and *Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf), which provide additional information regarding medical devices utilizing off-the-shelf software.

Overall, the documentation related to the software contained in the medical device should, among other things, provide sufficient evidence to describe the role of the software included in the device, and performance testing to demonstrate that the software functions as designed.

D. Biocompatibility

Ultrasonic diathermy devices contain patient-contacting materials, which, when used for their intended purpose (i.e., contact type and duration), could induce a harmful biological response. You should determine the biocompatibility of all patient-contacting materials present in your device. If the device is identical in composition and processing to a legally marketed predicate device with a history of successful use, you may reference previous testing experience or literature, if appropriate.

If you are unable to identify a legally marketed predicate device intended for use with a similar location/duration of contact that uses the same materials as used in your device, we recommend that you conduct and provide a biocompatibility risk assessment. The assessment should explain the relationship between the identified biocompatibility risks, the information available to mitigate the identified risks, and any knowledge gaps that remain. You should then provide any biocompatibility testing or other evaluations that were conducted to mitigate any remaining risks.

We recommend that you follow FDA's guidance *Use of International Standard ISO-10993, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*,' (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf), which identifies the types of biocompatibility assessments that should be considered and recommendations regarding how to conduct related tests.

Per ISO 10993-1 and FDA's guidance (Attachment A), ultrasonic diathermy devices are considered "Surface device," "Intact skin," "A – limited" contact duration. Therefore, the following endpoints should be addressed in your biocompatibility evaluation:

- Cytotoxicity
- Skin sensitization
- Irritation testing

Differences in formulation, processing, sterilization, or device surface properties (e.g., nano structuring) that could affect biocompatibility of the final product might warrant additional biocompatibility evaluation and testing.

In addition, ultrasonic diathermy device 510(k) submissions should include the following information about the transmission media used with the ultrasonic diathermy device:

Transmission media such as an acoustic coupling gel is used to acoustically couple the transducer to the body surface. Such gel is considered a device under the FD&C Act, and thus, the gel must have marketing clearance.[2] If the gel already has received marketing clearance, the 510(k) number should be provided. If the gel has not received marketing clearance, an appropriate predicate device(s) must be identified. In general, to establish substantial equivalence as required by section 513(f) of the FD&C Act, you must identify a predicate device with the same intended use and technological characteristics (such as measured sound velocity, acoustic impedance, and sound attenuation) to compare with the subject coupling gel (see section 513(i) of the FD&C Act). In addition, the gel formulation; biocompatibility evaluation; labeling, including directions for use and shelf life/expiration information, should be provided.

[2] It should be noted ultrasound coupling media are cleared under 21 CFR 892.1570, product code MUI.

E. Electrical Safety and Electromagnetic Compatibility (EMC)

Ultrasonic diathermy devices are medical electrical equipment and therefore may fail to operate properly in the presence of electromagnetic disturbance. Ultrasonic diathermy devices should be tested to demonstrate that they perform as intended anticipated in their intended use environment. We recommend that this testing be performed as described in the currently FDA-recognized versions of the following standards for medical electrical equipment safety and electromagnetic compatibility:

- AAMI ANSI ES60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- AAMI ANSI IEC 60601-1-2: *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*

If submitting a declaration of conformity under section 514(c) of the FD&C Act to the above standards, we recommend that appropriate supporting test data and analysis be provided because this series of standards includes general methods with multiple options and, in some cases, does not include specific acceptance criteria or address assessment of results. For additional information on providing electromagnetic compatibility information in a premarket submission, please see FDA's guidance, *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM470201.pdf.)

F. Wireless Technology

If your ultrasonic diathermy device incorporates radiofrequency wireless technology such as Bluetooth, IEEE 802.11 (Wi-Fi™) or RFID (radio frequency identification) technology, testing beyond what is specified in the IEC 60601 standards (referenced in section V.E. above) is recommended to demonstrate that the wireless device functions will perform as intended in environments with other wireless products. In the design, testing, and use of wireless medical devices, the correct, timely, and secure transmission of medical data and information is essential for the safe and effective use of both wired and wireless medical devices and systems. Particular points to address include quality of service needed, data integrity, coexistence, security, and EMC of the wireless signals. Due to the increased use of RF wireless technology that operates in the same frequency range, you should carefully address RF wireless coexistence through testing of the device with other common applications of RF wireless technology that can be expected to be present in the environment of use. If your device or system is expected to have two or more like devices operating wirelessly in close proximity to one another (e.g., mobile or body worn devices located in a waiting room or the same room of a home), the ability to so operate should also be tested. We recommend that you consult FDA's guidance, *Radio-Frequency Wireless*

Technology in Medical Devices (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf) for additional recommendations on this topic.

G. Labeling

The premarket notification must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels and labeling sufficient to describe the ultrasonic diathermy device, its intended use, and the directions for use must be provided. As a prescription device, ultrasonic therapy devices are exempt from having adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)) as long as the conditions in 21 CFR 801.109 are met. For instance, labeling must include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions. (21 CFR 801.109(d)).

In addition to the labeling requirements in 21 CFR part 801 and 1010.2 and 1010.3, each ultrasonic therapy product is subject to the labeling requirements in 21 CFR 1050.10(d). These labeling requirements are:

1) The generator housing must include a legible or clearly visible tag or label permanently affixed or inscribed with the following information (21 CFR 1050.10(d)(3), 21 CFR 1050.10(d)(5), and 21 CFR 1010.3(a)):
    a) the full name and address of the manufacturer of the device;
    b) the place and month and year of manufacture (e.g. Manufactured: <Insert Month and Year of Manufacture>);
    c) the brand name, model designation, and unique serial number or other unique identification so that it is individually identifiable;
    d) the acoustic working frequencies (unless there is an operation control for varying this quantity);
    e) the type of waveform (e.g. continuous wave or amplitude modulated); and
    f) for amplitude modulated waveforms, a description or picture of the output waveform, along with values for the pulse duration, pulse repetition period, and duty factor. If multiple modulation settings are possible, then the description or picture should be for the minimum duty factor.
2) Each applicator must bear the following information; its rated output power in watts, the acoustic working frequencies, the effective radiating area in square centimeters, the beam non-uniformity ratio, the beam type, and a designation of the specific generator of the equipment for which the treatment head is intended. (21 CFR 1050.10(d)(4)). In addition, the brand name, model designation, and unique serial number or other unique identification must be included so that it is individually identifiable.
3) Each operation control must be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. (21 CFR 1050.10(d)(1)). If a separate

control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.

4) Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product must be clearly labeled, identifying the function controlled and must include the phrase "for service adjustment only." (21 CFR 1050.10(d)(2)).

(1) Contraindications

Based on known risks associated with this device type, we recommend including the following contraindications, as applicable, in the instructions for use. Sample language is provided in italics. If you believe that any of these contraindications are not applicable to your device, you should provide a justification for each omission in your 510(k) submission.

1. *Patients with an implanted medical device other than a pacemaker such as implanted deep brain stimulation device*
2. *Near brain, cervical ganglia, spine, laminectomy sites (can cause spinal-cord heating)*
3. *Near the reproductive organs*
4. *Total hip arthroplasties with methylmethacrylate or high density polyethylene. These have a high coefficient of absorption, more than soft tissue, and the prosthesis could loosen due to unstable cavitation in the cement*
5. *Arthroplasties—the effect on bony ingrowth arthroplasties is not well defined; for this reason the most prudent course is avoiding ultrasonic therapy over these areas*
6. *Over or near bone growth centers until bone growth is complete*
7. *Over the thoracic area if the patient is using a cardiac pacemaker*
8. *In an area of the body where a malignancy is known to be present*
9. *In an area of the body where infectious disease is present*
10. *Blood vessels in poor condition should not be treated as the vessel walls could rupture as a result of the exposure*
11. *Patients suffering from cardiac disease should not receive treatment over the cervical ganglia, the stellate ganglion, the thorax in the region of the heart, or the vagus nerve, as a reflex coronary vasospasm might result. Only low intensities and short treatment times should be used if these patients are treated in other areas because the stimulation of practically any afferent autonomic nerve (especially the vagus nerve) in the body could cause a change in cardiac rate*
12. *Patients with thrombophlebitis or other potentially thromboembolic diseases should not be treated because a partially disintegrated clot could result in an obstruction of the arterial supply to the brain, heart or lungs*
13. *Over a healing fracture*
14. *Over the eye*
15. *Over the pregnant uterus*
16. *Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand*
17. *Over areas of recent bleeding or hemorrhage*
18. *Over areas of active tuberculosis*

(2) Warnings

We recommend including the following warnings in the instructions for use.

1. *The treatment head should be moved continuously during treatment to avoid discomfort and burns.*
2. *An appropriate coupling medium should be used in order to ensure energy transmission to the tissue.*

(3) Precautions

We recommend including the following precautions in the instructions for use regarding use of the device over these areas or on patients with these conditions.

1. *Over anesthetized areas*
2. *On patients with hemorrhagic diatheses*
3. *Over areas where there is sensory impairment or sensory loss*
4. *Over acute skin conditions such as eczema, dermatitis, etc*
5. *Over the anterior aspect of the neck*
6. *On patients who are febrile*

H. Cleaning and Reprocessing

Under section 502(f)(1) of the FD&C Act and its implementing regulations found in 21 CFR Part 801, a device must have adequate directions for use, which include instructions on preparing a device for use. *See* 21 CFR 801.5(g). Prescription devices are exempt from this adequate directions for use requirement as long as certain conditions are met, including that the labeling bear "information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended…" 21 CFR 801.109(d). Instructions on how to reprocess a reusable device are critical to ensure that a device is appropriately prepared for its initial and subsequent uses; and thus, such instructions are considered a condition for exemption from adequate directions for use under 21 CFR 801.109. For recommendations regarding the development and validation of reprocessing instructions in your proposed device labeling, please refer to FDA guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf).

APPENDIX A

Glossary of Terms

For the purposes of this guidance, the following terminology and definitions are provided to facilitate consistency.

Active Area Coefficient
quotient of the active area gradient, m, and the beam cross-sectional area at 0,3 cm from the face of the treatment head, ABCS(0,3)

Active Area Gradient
gradient of the line connecting the beam cross-sectional area at 0,3 cm from the face of the treatment head, ABCS(0,3), and the beam cross-sectional area at the position of the last axial maximum acoustic pressure, ABCS(zN), versus distance

Amplitude Modulated Wave
wave in which the ratio $p_p / \sqrt{2}p_{rms}$ at any point in the far field on the beam alignment axis is greater than 1.05, where p_p is the temporal-peak acoustic pressure and p_{rms} is the r.m.s. acoustic pressure

Acoustic Working Frequency
frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field. The signal is analyzed using the zero-crossing frequency technique

Attachment Head
accessory intended to be attached to the treatment head for the purpose of modifying the ultrasonic beam characteristics

Beam Axis
straight line joining two points of spatial-peak temporal-peak acoustic pressure on two plane surfaces parallel to the faces of the treatment head. One plane is at a distance of approximately $ERA/(\pi\lambda)$ where *ERA* is the Effective Radiating Area of the treatment head and λ is the wavelength of the ultrasound corresponding to the nominal value of the acoustic-working frequency. The second plane surface is at a distance of either $2ERA/(\pi\lambda)$ or $ERA/(3\pi\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the treatment head

Beam Maximum Intensity
product of the beam non-uniformity ratio and effective intensity
Note 1: Beam maximum intensity is expressed in watt per square meter (W/m^2).

Beam Non-uniformity Ratio (BNR)

ratio of the square of the maximum r.m.s. acoustic pressure to the spatial average of the square of the r.m.s. acoustic pressure, where the spatial average is taken over the effective radiating area

Beam Type
descriptive classification for the ultrasonic beam in one of three types: collimated, convergent or divergent

Collimated
beam for which the **active area coefficient**, Q, obeys the following inequality: $-0.05\ \text{cm}^{-1} \leq Q \leq 0.1\ \text{cm}^{-1}$

Continuous Wave
wave in which the ratio $p_p/\sqrt{2}p_{rms}$, at any point in the far field on the beam alignment axis, is less than or equal to 1.05, where p_p is the temporal-peak acoustic pressure and p_{rms} is the r.m.s. acoustic pressure

Divergent
beam for which the **active area coefficient**, Q, obeys the following inequality: $Q > 0.1\ \text{cm}^{-1}$

Duty Factor
ratio of the pulse duration to the pulse repetition period

Effective Intensity
intensity given by $I_e = P/A_{ER}$ where P is the output power and A_{ER} is the effective radiating area

Effective Radiating Area (ERA)
beam cross-sectional area determined at a distance of 0.3 cm from the front of the treatment head, $A_{BCS}(0,3)$, multiplied by a dimensionless factor, equal to 1.354
Note 1: Beam cross-sectional area is expressed in centimeter squared (cm^2).
Note 2: This may be thought of as the area of the face of the treatment head which transmits 100% of the total output power.

Last Axial Maximum Acoustic Pressure
The last spatial relative maximum rms acoustic pressure measured outward from the transducer, along the Beam Axis

Output Power
time-average ultrasonic power emitted by a treatment head of ultrasonic physiotherapy equipment into an approximately free field under specified conditions in a specified medium, preferably in water
Note: Output power is expressed in watts (W).

Pulse Duration
time interval beginning at the first time the pressure amplitude exceeds a reference value and ending at the last time the pressure amplitude returns to that value. The reference value is equal

to the sum of the minimum pressure amplitude and 10% of the difference between the maximum and minimum pressure amplitude
Note: Pulse duration is expressed in seconds (s).

Pulse Repetition Period
time interval between two equal moments in time of successive pulses or tone-bursts
Note: Pulse repetition period is expressed in seconds (s).

Rated Output Power
maximum output power of the ultrasonic physiotherapy equipment at the rated value of the mains voltage, with control settings configured to deliver maximum output power
Note: Rated output power is expressed in watts (W).

Temporal-Maximum Intensity
in the case of an amplitude modulated wave, the ratio of the temporal-maximum output power to the effective radiating area

Temporal-Maximum Output Power
in the case of an amplitude modulated wave, a function of the actual output power, the temporal-peak acoustic pressure and the r.m.s. acoustic pressure. (It is equal to the output power divided by the duty factor.)

Treatment Head
assembly comprising an ultrasonic transducer and associated parts for local application of ultrasound to the patient.
Note: A treatment head is also referred to as an applicator.

Ultrasound
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 16 kHz)

Ultrasonic Physiotherapy Equipment (also referred to as equipment)
equipment for the generation and application of ultrasound to a patient for therapeutic purposes
Note: Essentially the equipment comprises a generator of electric high-frequency power and a transducer for converting this to ultrasound.

Ultrasonic Transducer
device component capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally of converting mechanical energy to electrical energy.