



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2012-N-0378]

Physical Medicine Devices; Reclassification of Shortwave Diathermy for All Other Uses, Henceforth To Be Known as Nonthermal Shortwave Therapy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; technical correction.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify shortwave diathermy (SWD) for all other uses, a preamendments class III device, into class II (special controls), and to rename the device "nonthermal shortwave therapy" (SWT). FDA is also making a technical correction in the regulation for the carrier frequency for SWD and SWT devices.

DATES: This order is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See further discussion in Section IV, "Implementation Strategy."

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SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act (Pub. L. 108-214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as "postamendments devices"), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or

FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e), includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. United States Department of Health, Education, and Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see Bell, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 388-391 (D.D.C. 1991); or, in light of changes in "medical science," Upjohn, 422 F.2d at 951). Whether data before the Agency are old or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence" as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., Gen. Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).)

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final reclassification order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA published a proposed order to reclassify this device in the Federal Register of February 20, 2014 (79 FR 9671). FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act to discuss shortwave diathermy for all other uses, and therefore, has met this requirement under section 513(e)(1) of the FD&C Act. As explained further in section II of the proposed order, a meeting of a device classification panel described in section 513(b) of the FD&C Act took place on May 21, 2013.

FDA received and has considered several comments on this proposed order, as discussed in Section II.

II. Public Comments in Response to the Proposed Order

In response to the February 20, 2014, proposed order to reclassify shortwave diathermy for all other uses and to rename the device "nonthermal shortwave therapy," FDA received 40 comments from industry, a patient advocacy group, and consumers of SWT devices. Of those, 35 comments were received from users of specific devices who support the use and availability of those devices in the United States. Several of these comments also supported reclassification into class II. This final order reclassifies into class II SWT devices intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues and establishes special controls that are intended to mitigate risks to health of SWT devices in order to provide a reasonable assurance of their safety and effectiveness. These special controls are meant to protect patients from unsafe or ineffective SWT devices.

Six of the comments from users also requested that the prescription use restriction be removed from the proposed regulation so that SWT devices could be available over-the-counter (OTC). This final order applies only to SWT devices for the indications and uses that have been previously cleared for marketing. To date, FDA has not cleared an SWT device for OTC use and, as a result, has limited the reclassification in this final order to prescription use devices. However, if FDA receives a marketing application in the future for an SWT device indicated for OTC use, FDA would make its classification decision regarding such use at that time.

One public comment FDA received requested that SWT devices remain classified in class III, and that FDA call for PMAs. FDA disagrees that SWT devices should remain in class III

and require PMA approval. On May 21, 2013, FDA held a meeting of the Orthopedic and Rehabilitation Devices Panel (the 2013 Panel), to discuss the classification of SWT devices (Ref. 1). The 2013 Panel reached consensus that SWT devices did not fit the statutory definition of a class III device. Section 513(a)(1)(C) of the FD&C Act provides that a device is class III if (a) the device is life supporting or life sustaining, of substantial importance in preventing impairment to human health, or presents a potential unreasonable risk of illness or injury, and (b) the device cannot be classified in class I or II because insufficient information exists to determine that general controls or general and special controls would provide reasonable assurance of the safety and effectiveness of the device. The 2013 Panel agreed that SWT devices are not life supporting or life sustaining, or of substantial importance to preventing impairment to human health. The 2013 Panel was concerned about the potential unreasonable risk of illness or injury resulting from the use of SWT devices in certain instances, such as treatments around the eye. Moreover, the 2013 Panel concluded that the information presented to the panel was sufficient to establish special controls that are necessary to provide reasonable assurance of safety and effectiveness of SWT. Thus, the consensus of the 2013 Panel was to recommend that SWT be reclassified into class II (special controls).

FDA agrees with the 2013 Panel's recommendation for reclassification. The Agency believes, as stated in the proposed order, that the risks of SWT devices are sufficiently understood based on valid scientific evidence, and a review of the clinical literature indicates that few relevant adverse events have been reported for these devices. FDA further believes that the risks of SWT devices with the special controls identified in this final order will be nominal.

One of the public comments, received from industry, requested removal of the special control requiring clinical data, stating that it was unnecessary and there was already sufficient

evidence of effectiveness. This comment did not cite new data, but requested that FDA reconsider the data that was previously presented to the 2013 Panel. The available scientific evidence on the effectiveness of SWT was presented to the 2013 Panel by both FDA and industry, and there was panel consensus that the existing data was very limited and that clinical data should be required as a special control. When asked to consider the benefits of SWT based on the information presented to it by FDA and industry, the 2013 Panel consensus was that there may be a certain subset of patients who may benefit from SWT; however, the 2013 Panel had "very serious concerns involving both the veracity and the scientific methodology of the data presented." Thus, although the limited data reviewed by the Agency and by the 2013 Panel suggest that SWT could potentially be effective, particularly for management of postoperative pain, the 2013 Panel members indicated a need for clinical data demonstrating effectiveness from statistically powered, well-controlled studies with quantified outcomes. The 2013 Panel agreed with FDA that clinical studies should consider the following attributes: Randomization, utilization of sham controls, blinding, well-defined cohorts, well-defined treatment parameters, clinically relevant and validated measures, adequate power, appropriate and defined methods of statistics, predefined hypotheses, and systematic collection of adverse events. The 2013 Panel believed that clinical studies incorporating these basic design elements should be feasible to conduct, and are important in demonstrating an appropriate level of effectiveness for specific devices. FDA agrees with the 2013 Panel's assessment and has determined that the special controls identified in this final order, including clinical performance data, are necessary to provide a reasonable assurance of safety and effectiveness of SWT.

Two comments from sponsors of currently marketed SWT devices supported reclassification, but requested 2 years from the effective date of the final order to submit a

510(k), rather than the 60 days FDA proposed in the proposed order. The comments suggested that if clinical data are necessary, it will be difficult to plan and conduct a clinical trial and submit the data within 60 days of the effective date of the final order. One comment suggested that it will be beneficial to interact with the Agency prior to a clinical trial and submission of the data to FDA, and that 60 days may not be adequate to accomplish such. FDA would like to encourage interaction with the Agency prior to a clinical study and submission of the data to FDA, and therefore grants these requests to provide more time for currently legally marketed SWT devices to comply with the special controls identified in this order. The special controls will be effective on the date of publication of this final order. However, FDA does not intend to enforce compliance with the special controls with respect to currently legally marketed SWT devices until 1 year after the date of publication of this final order. Please see Section IV, "Implementation Strategy." The Agency also notes that when indicated for adjunctive use in the palliative treatment of postoperative pain and edema, SWT devices may not be considered significant risk devices, per 21 CFR 812.3(m), and therefore clinical studies conducted in the United States involving SWT devices with those indications for use may not require an application for Investigational Device Exemption (U.S. studies involving such devices would, however, require approval by an institutional review board; see 21 CFR 812.2(b)(1)). Alternatively, SWT devices with indications for use different from adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue, or that specify the types of postoperative pain or edema, may be considered significant risk devices. We encourage interaction with FDA through the presubmission process to address any questions regarding whether such a device is significant risk.

One industry comment challenged FDA's authority to require new 510(k)s for SWT devices that have already been legally marketed to demonstrate that the SWT devices meet the special controls. FDA has considered this comment, and will not require manufacturers of currently legally marketed SWT devices to submit a new 510(k) notification. However, manufacturers must comply with the special controls implemented by this order; if the special controls are not met then the device may be considered adulterated under section 501(f)(1)(B) of the FD&C Act (21 U.S.C. 351(f)(1)(B)). In order to ensure compliance with these special controls, FDA is requiring that manufacturers of currently marketed SWT devices submit an amendment to their previously cleared 510(k) demonstrating compliance with the special controls. Such amendment will be added to the 510(k) file but will not serve as a basis for a new substantial equivalence review. An amendment to a 510(k) in this context will be used solely to submit information demonstrating to FDA that an SWT device is in compliance with the special controls.

As discussed above, the special controls will be effective on the date of publication of this final order. However, FDA does not intend to enforce compliance with the special controls with respect to currently legally marketed SWT devices until 1 year after the date of publication. Please see Section IV, "Implementation Strategy." If an amendment to a 510(k) that demonstrates compliance with the special controls for the device is not submitted as required in Section IV or if FDA determines after review of the amendment that the device is not in compliance with the special controls, the device may be considered adulterated and sale of the device would have to cease.

In reviewing the proposed order, the comments received, and the 2013 Panel's recommendations, FDA is also making a few modifications to the identification and special

controls for SWT devices. The identification has been revised from "intended for the treatment of medical conditions except for the treatment of malignancies" to "intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue," as the latter statement more closely captures the current intended uses of existing SWT devices. The special control that specifies saline gel test loads has been revised to allow for testing in saline gel test load or other appropriate models to allow for flexible characterization approaches. The special control "Documented clinical performance testing must demonstrate safe and effective use of the device" has been revised to "A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device in its intended use." This revision clarifies the information that FDA would expect to see under this special control. Finally, labeling for SWT devices must include output characteristics of the device and recommended treatment regimes, including duration of use, in addition to a detailed summary of the clinical testing pertinent to the use of the device and a summary of the adverse events and complications. This revision clarifies the type of information that FDA would expect to see in labeling for SWT devices. FDA believes these revisions provide additional clarification and flexibility for SWT device manufacturers.

III. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the preamble to the proposed order with the modifications discussed in Section II of this final order. FDA is issuing this final order to reclassify shortwave diathermy (SWD) for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue by means other than the generation of deep heat within body tissues from class III to class II, rename the device "nonthermal shortwave therapy" (SWT), and establish special controls by revising part 890 (21

CFR part 890). As described in the proposed order, FDA is also making a technical correction in the regulation for the carrier frequency for SWD and SWT devices from "13 megahertz (MHz) to 27.12 MHz" to "13.56 MHz or 27.12 MHz." The identification for § 890.5290 has been revised to provide the name change of the device under paragraph (b) and a more accurate description of the devices in this classification section. SWT devices must comply with the special controls identified in this order (see Section IV, "Implementation Strategy").

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of SWT and, therefore, this device type is not exempt from premarket notification requirements.

Following the effective date of this final order, firms marketing SWT devices must comply with the special controls set forth in this order (see Section IV, "Implementation Strategy").

IV. Implementation Strategy

The special controls identified in this final order are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For models of SWT devices that have not been legally marketed prior to [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], or models that have been legally marketed but are required to submit a new 510(k) under § 807.81(a)(3) because the device is about to be significantly changed or modified, manufacturers must obtain 510(k) clearance, among other relevant requirements, and

demonstrate compliance with the special controls included in this final order, before marketing the new or changed device.

FDA does not intend to enforce compliance with the special controls for currently legally marketed SWT devices until [INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For those manufacturers who wish to continue to offer currently legally marketed devices for sale, FDA expects them to submit a 510(k) amendment for those devices by [INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] demonstrating compliance with the special controls included in this final order. If a 510(k) amendment is not submitted by this date for the device or if FDA determines that the amendment does not demonstrate compliance with the special controls, the device may be considered adulterated under section 501(f)(1)(B) of the FD&C Act as of the date of FDA's determination of noncompliance or [INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], whichever is sooner, and sale of the device would have to cease.

V. Environmental Impact, No Significant Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number

0910-0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order we are revoking the requirements in § 890.5290(b) related to the classification of SWT as class III devices and codifying the reclassification of SWT into class II (special controls).

VIII. Reference

FDA has placed the following reference on display in the Division of Dockets Management (HFA-305) Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Interested persons may see it between 9 a.m. and 4 p.m., Monday through Friday, and online at <http://www.regulations.gov>.

1. FDA's Orthopedic and Rehabilitation Devices Panel transcript and other meeting materials are available on FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/>

[MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm](https://www.fda.gov/oc/medical-devices/medical-devices-advisory-committee/orthopaedic-and-rehabilitation-devices-panel/ucm352525.htm).

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890--PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 890.5290 is amended by revising paragraphs (a)(1) and (b) and removing paragraph (c).

The revisions read as follows:

§ 890.5290 Shortwave diathermy.

(a) Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions—(1) Identification. A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radiofrequency (RF) bands of 13.56 megahertz (MHz) or 27.12 MHz 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.

* * * * *

(b) Nonthermal shortwave therapy—(1) Identification. A nonthermal shortwave therapy is a prescription device that applies to the body pulsed electromagnetic energy in the RF bands of

13.56 MHz or 27.12 MHz and that is intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) Classification: Class II (special controls). The device is classified as class II. The special controls for this device are:

(i) Components of the device that come into human contact must be demonstrated to be biocompatible.

(ii) Appropriate analysis/testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(iii) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Non-clinical performance testing must characterize the output waveform of the device and demonstrate that the device meets appropriate output performance specifications. The output characteristics and the methods used to determine these characteristics, including the following, must be determined:

- (A) Peak output power;
- (B) Pulse width;
- (C) Pulse frequency;
- (D) Duty cycle;
- (E) Characteristics of other types of modulation that may be used;
- (F) Average measured output powered into the RF antenna/applicator;
- (G) Specific absorption rates in saline gel test load or other appropriate model;
- (H) Characterization of the electrical and magnetic fields in saline gel test load or other appropriate model for each RF antenna and prescribed RF antenna orientation/position; and

(I) Characterization of the deposited energy density in saline gel test load or other appropriate model.

(iv) A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device in its intended use.

(v) Labeling must include the following:

(A) Output characteristics of the device;

(B) Recommended treatment regimes, including duration of use; and

(C) A detailed summary of the clinical testing pertinent to the use of the device and a summary of the adverse events and complications.

(vi) Nonthermal shortwave therapy devices marketed prior to the effective date of this reclassification must submit an amendment to their previously cleared premarket notification (510(k)) demonstrating compliance with these special controls.

Dated: October 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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