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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

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

Physical Medicine Devices; Withdrawal of Proposed Effective Date of Requirement for Premarket Approval for Shortwave Diathermy for All Other Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the Agency issued in the Federal Register of July 6, 2012. In that document, FDA proposed to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the class III preamendment device, shortwave diathermy (SWD) for all other uses. In response to the requirements issued in the Food and Drug Administration Safety and Innovation Act (FDASIA) and new information received during a panel meeting, FDA is withdrawing the proposed rule and proposing a different action.

DATES: The proposed rule is withdrawn on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993, 301-796-5616, Melissa.Burns@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

In the Federal Register of July 6, 2012 (77 FR 39953), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the class III preamendments device, SWD for all other uses. This device applies electromagnetic energy to the body in the radio frequency bands that are currently identified as 13.56 megahertz or 27.12 megahertz and is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues (also referred to as nonthermal SWD). It is not intended for treatment of malignancies. The Agency also summarized its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA announced the opportunity for interested persons to request that the Agency change the classification of any of the aforementioned devices based on new information.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) (U.S.C. 360c(e)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA’s amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting on the classification of this device. On May 21, 2013, FDA held a meeting of the Orthopedic and Rehabilitation Devices Panel (the Panel), to discuss the classification of nonthermal SWD devices. There was panel consensus that although the effectiveness data were very limited, nonthermal SWD devices did not fit the regulatory definition of a class III device. Coupled with the rationale that special controls could be established to reasonably demonstrate an assurance of

safety and effectiveness, the Panel recommended class II (special controls) for nonthermal SWD devices (Ref. 1).

II. Withdrawal of the Proposed Rule

FDA provided an opportunity for interested parties to comment on the proposed rule for SWD for all other uses (77 FR 39953, July 6, 2012). FDA received over 240 comments to the docket in response to the 2012 proposed rule. Comments that expressed an opinion about the classification of nonthermal SWD devices were usually in favor of a class II designation. Some comments did not openly state an opinion, but included arguments against the proposed rule that could reasonably be interpreted as support for a class II designation. There were also comments that agreed with a class III designation. In addition to the comments, FDA received five separate submissions to request a change in the classification of nonthermal SWD from class III to class II. In response to these comments and findings at the Panel meeting, FDA is withdrawing the proposed rule to call for PMAs for these devices and is proposing reclassification to class II (special controls).

III. Proposed Reclassification

Elsewhere in this issue of the Federal Register, FDA is proposing to reclassify SWD for all other uses, currently a preamendments class III device, into class II (special controls), and to rename the device "nonthermal shortwave therapy." FDA continues to review the merits of the submissions for requests for reclassification that meet the requirements under 21 CFR 860.123, submitted in response to the proposed rule.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4

p.m., Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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.

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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