4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA 2016-N-2677]

Medical Devices; Neurological Devices; Classification of the Evoked Photon Image Capture Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Evoked Photon Image Capture Device into class I (general controls). The Agency is classifying the device into class I (general controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Kristen Bowsher, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2646, Silver Spring, MD, 20993-0002, 301-796-6448, kristen.bowsher@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred

to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), 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 part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)), as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-

moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device. On January 12, 2015, EPIC Research & Diagnostics, Inc. submitted a request for classification of the EPIC ClearView™ System under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class I if general controls by themselves are sufficient to provide reasonable assurance of safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class I. FDA believes general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 15, 2016, FDA issued an order to the requestor classifying the device into class I. FDA is codifying the classification of the device by adding 21 CFR 882.1561.

The device is assigned the generic name evoked photon image capture device, and it is identified as a prescription, electrically-powered device intended for use as a non-invasive measurement tool that applies electricity to detect electrophysiological signals emanating from the skin, which are reported numerically and as images without clinical interpretation. The device is not intended for diagnostic purposes.

FDA has identified the following risks to health associated specifically with this type of device: Adverse tissue reaction, electromagnetic incompatibility, and electromagnetic malfunction (e.g., shock).

Evoked photon image capture devices are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 Prescription devices).

II. Analysis of Environmental 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.

III. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in other 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 part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882--NEUROLOGICAL DEVICES

1. The authority citation for part 882 continues to read as follows:

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

2. Add § 882.1561 to subpart B to read as follows:

§ 882.1561 Evoked photon image capture device.

(a) Identification. An evoked photon image capture device is a prescription, electrically powered device intended for use as a noninvasive measurement tool that applies electricity to detect electrophysiological signals emanating from the skin, which are reported numerically and as images without clinical interpretation. The device is not intended for diagnostic purposes.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 882.9.

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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