4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2015-P-1197]

Medical Devices; Exemption from Premarket Notification; Class II Devices; Electric Positioning Chair

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is publishing an order granting a petition requesting exemption from premarket notification requirements for electric positioning chair devices. An electric positioning chair is a device with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. These devices are used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions. This order exempts electric positioning chairs, class II devices, from premarket notification, subject to certain conditions for exemption. This exemption from premarket notification, subject to these conditions (and the limitations in the physical medicine devices limitations of exemptions from premarket notification section of the device regulations), is immediately in effect for electric positioning chairs. FDA is publishing this order in accordance with the exemption from class II premarket notification section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Marszalek, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1427, Silver Spring, MD 20993, 301-796-7067.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations (21 CFR part 807) require persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a premarket notification (510(k)) to FDA. The device may not be marketed until FDA finds it "substantially equivalent" within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 206 of FDAMA added section 510(m) to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the Federal Register a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the Federal Register. FDA published that list in the Federal Register of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a device from premarket notification requirements on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to assure the safety and effectiveness of the device. This section requires FDA to publish in the Federal Register a notice of intent to

exempt a device, or of the petition, and to provide a 30-day comment period. FDA must publish in the Federal Register its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to assure the safety and effectiveness of a class II device. These factors are discussed in the guidance that the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff" (Class II 510(k) Exemption Guidance). That guidance can be obtained through the Internet on the Center for Devices and Radiological Health home page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080198.htm or by sending an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

III. Device Description

Electric positioning chairs are devices with a motorized positioning control that are intended for medical purposes and that can be adjusted to various positions. Existing legally marketed devices have identified a range of specific procedures or conditions for which an electric positioning chair could be used to provide stability and to alter postural positions (e.g., muscular dystrophy, Parkinson's syndrome, or joint replacements). The devices are primarily intended to provide stability and a controlled lift from a seated position to a standing position, while supporting the patient's weight (alter postural positions). The device consists of a frame

(where the user would sit) and a lift mechanism, and may also allow the patient to recline in the device.

IV. Petition

On April 10, 2015, FDA received a petition requesting an exemption from premarket notification for electric positioning chair devices. (See Docket No. FDA-2015-P-1197.) These devices are currently classified under 21 CFR 890.3110 Electric positioning chair.

In the Federal Register of June 12, 2015 (80 FR 33525), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by July 13, 2015. FDA received no comments.

FDA has assessed the need for 510(k) clearance for this type of device using the criteria laid out in the Class II 510(k) Exemption Guidance and in the January 21, 1998, notice (63 FR 3142 at 3143). Based on its review, FDA believes that premarket notification is not necessary to assure the safety and effectiveness of the device, as long as certain conditions are met. FDA believes that the risks posed by the device (such as instability, entrapment, use error, falls and associated injuries, battery/electrical/mechanical failure, pressure sores, bruising, burns, electric shock, and electromagnetic incompatibility/interference) and the characteristics of the device necessary for its safe and effective performance (such as safety features, weight capacity, power source, drive mechanism/actuator, and user controls) are well established. Moreover, FDA believes that changes in the device that could affect safety and effectiveness will be readily detectable by certain types of routine analysis and non-clinical testing, such as those detailed in certain consensus standards. Therefore, after reviewing the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of electric positioning chairs, as long as the conditions for 510(k) exemption in section V are met. FDA

responded to the petition by letter dated October 9, 2015, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

V. Conditions for Exemption

This final order provides conditions for exemption from premarket notification. The following conditions must be met for the device to be 510(k)-exempt: (1) Appropriate analysis and non-clinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure; (2) appropriate analysis and non-clinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety; (3) appropriate analysis and non-clinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device; (4) appropriate analysis and non-clinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device; (5) appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ANSI/AAMI ES60601-1: "Medical Electrical Equipment--Part 1: General Requirements for Basic Safety and Essential Performance," and ANSI/AAMI/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") must validate electromagnetic compatibility and electrical safety; (6) appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices--Part 1: Evaluation and Testing Within a Risk Management Process," ANSI/AAMI/ISO 10993-5, "Biological Evaluation of Medical Devices--Part 5: Tests for In Vitro Cytotoxicity," and ANSI/AAMI/ISO 10993-10, "Biological Evaluation of Medical

Devices--Part 10: Tests for Irritation and Skin Sensitization") must validate that the skin-contacting components of the device are biocompatible; (7) appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of IEC 62304, "Medical Device Software--Software Life Cycle Processes") must validate the software life cycle and that all processes, activities, and tasks are implemented and documented; (8) appropriate analysis and non-clinical testing must validate that the device components are found to be non-flammable; (9) appropriate analysis and non-clinical testing must validate that the battery in the device (if applicable) performs as intended over the anticipated service life of the device; and (10) adequate patient labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device by the patient in the intended use environment.

Firms are now exempt from 510(k) requirements for electric positioning chairs as long as they meet these conditions of exemption, subject to the limitations in 21 CFR 890.9. Firms must comply with the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

VII. 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 801, regarding medical device labeling, have been

approved under OMB control number 0910-0485 and the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910-0073.

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. In § 890.3110, revise paragraph (b) to read as follows:

§ 890.3110 Electric positioning chair.

* * * * *

(b) Classification. Class II. The electric positioning chair is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9 and the following conditions for exemption:

(1) Appropriate analysis and non-clinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and non-clinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and non-clinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device;

(4) Appropriate analysis and non-clinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ANSI/AAMI/ ES60601-1, "Medical Electrical Equipment--Part 1: General Requirements for Basic Safety and Essential Performance," and ANSI/AAMI/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") must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices--Part 1: Evaluation and Testing Within a Risk Management Process," ANSI/AAMI/ISO 10993-5, "Biological Evaluation of Medical Devices--Part 5: Tests for In Vitro Cytotoxicity," and ANSI/AAMI/ISO 10993-10, "Biological Evaluation of Medical Devices--Part 10: Tests for Irritation and Skin Sensitization") must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of IEC 62304, "Medical Device Software--Software Life Cycle Processes") must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and non-clinical testing must validate that the device components are found to be non-flammable;

(9) Appropriate analysis and non-clinical testing must validate that the battery in the device (if applicable) performs as intended over the anticipated service life of the device; and

(10) Adequate patient labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device by the patient in the intended use environment.

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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