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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2019-P-3347]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Powered Wheeled Stretcher

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order granting a petition requesting exemption from premarket notification (510(k)) requirements for powered wheeled stretchers (product code INK). These devices are battery-powered tables with wheels that are intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions). This order exempts powered wheeled stretchers, class II devices, from 510(k) requirements, subject to certain conditions for exemption. This exemption from 510(k) requirements is immediately in effect for powered wheeled stretchers. FDA is publishing this order in accordance with the section of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

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

FOR FURTHER INFORMATION CONTACT: Eric Franca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD, 20993-0002, 301-796-4505, eric.franca@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807, subpart E (21 CFR part 807, subpart E) 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 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 (Pub. L. 105-115), section 206 of which added section 510(m) to the FD&C Act, which was amended on December 13, 2016, by the 21st Century Cures Act (Pub. L. 114-255). Section 510(m)(1) of the FD&C Act requires FDA to publish in the *Federal Register* a notice that contains 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 of the device. 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 510(k) 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 60-calendar-day period for public comment. Within 120 days after the issuance of the notice, FDA shall publish an order in the *Federal Register* setting forth the 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" (Class II 510(k) Exemption Guidance). That guidance can be obtained through the internet at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf 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. Petition

On July 10, 2019, FDA received a petition requesting an exemption from premarket notification for powered wheeled stretchers (see Docket No. FDA-2019-P-3347). These devices are currently classified under 21 CFR 890.3690, powered wheeled stretchers.

In the *Federal Register* of September 16, 2019 (84 FR 48623), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by November 15, 2019. FDA received no comments.

FDA has assessed the need for 510(k) clearance for this type of device against the criteria laid out in the Class II 510(k) Exemption Guidance. Based on this 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 and the characteristics of the device necessary for its safe and effective performance are well established. FDA believes that changes in the device that could affect safety and effectiveness will be readily detectable by visual examination. Therefore, after reviewing the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of powered wheeled stretchers, as long as the conditions in section IV are met. FDA responded to the petition by letter dated December 31, 2019, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Conditions for Exemption

This final order provides conditions for exemption from premarket notification for the powered wheeled stretcher.[1] The conditions that must be met for the device to be 510(k)-exempt are as follows: appropriate analysis and nonclinical 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; appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety; appropriate analysis and nonclinical 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; appropriate analysis and nonclinical testing must demonstrate proper environments

[1] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

of use and storage of the device to maximize the longevity of the device; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented; appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device; adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds and mitigation strategy to reduce entrapment.

A number of these conditions involve "appropriate analysis and nonclinical testing," the details of which are outlined in, among other places, certain FDA-recognized consensus standards. The following is a list of FDA recognized consensus standards that may be used to meet the listed conditions of exemption. Specifically, those standards include FDA-recognized editions of:

- ANSI/AAMI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- 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,
- ISO 7176-14: Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- ISO 7176-21: Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- 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
- AAMI/ANSI/ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- IEC 62304: Medical device software - Software life cycle processes
- ISO 7176-25: Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.

We also recommend you consider FDA's guidance entitled "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" when considering the appropriate risk assessment referenced in the conditions set forth above.

Firms are now exempt from 510(k) requirements for powered wheeled stretchers as long as they meet these conditions, subject to the limitations on exemption in 21 CFR 890.9. Firms must comply with the particular conditions set forth in the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

V. Analysis of 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.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved FDA collections of information. 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. 3501-3521). The collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073; 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 parts 801 and 809, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 890

Medical 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 part 890 continues to read as follows:

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

2. In § 890.3690, revise paragraph (b) to read as follows:

§ 890.3690 Powered wheeled stretcher.

* * * * *

(b) *Classification*. Class II (performance standards). The powered wheeled stretcher 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 nonclinical 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 nonclinical 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 nonclinical 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 nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable;

(9) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device;

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

(11) Appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds, and mitigation strategy to reduce entrapment.

Dated: January 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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