4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2011-P-0804]

# Medical Devices; Exemption From Premarket Notification; Class II Devices; Powered Patient Transport

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from premarket notification requirements for powered patient transport devices commonly known as stairway chair lifts. These devices are used to assist in the transfer of a person with a mobility impairment caused by injury or other disease up and down flights of stairs. This order exempts stairway chair lifts, class II devices, from premarket notification and establishes conditions for exemption for this device that will provide a reasonable assurance of the safety and effectiveness of the device without submission of a premarket notification (510(k)). This exemption from 510(k), subject to these conditions, is immediately in effect for stairway chair lifts. All other devices classified under FDA's powered patient transport regulations, including attendant-operated portable stair-climbing chairs (which are different from wheelchairs) continue to require submission of 510(k)s. FDA is publishing this order in accordance with the section of the Food, Drug, and Cosmetic Act (the 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:

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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 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) (Public Law 105-115), section 206 of which 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 provide reasonable assurance of 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 provide reasonable assurance of 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 dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 159 to identify the guidance you are requesting.

## III. Petition

On November 7, 2011, FDA received a petition requesting an exemption from premarket notification for powered patient transport devices commonly known as stairlifts. (See Docket No. FDA-2011-P-0804.) These devices are currently classified under § 890.5150 (21 CFR 890.5150), Powered patient transport. On May 3, 2012, FDA responded to the petition with a letter explaining that the information provided in the petition was insufficient for the Agency to assess whether the risks posed by this type of device could be sufficiently mitigated in the absence of premarket notification requirements. To address the Agency's concerns, the petitioner submitted additional information regarding standards that could be relied upon to mitigate the device risks, which the Agency received on June 19, 2012. This restarted the 180-day clock under section 510(m)(2) of the FD&C Act. (See Class II 510(k) Exemption Guidance, p. 3.)

In the Federal Register of June 1, 2012 (77 FR 32642), 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 2, 2012. FDA received one comment supporting an exemption from premarket notification for this type of device. The comment stated that these devices have been produced for many years and have a very good safety record. It noted that all of these products already need to comply with the FDA-recognized American Society of Mechanical Engineers (ASME) standard "ASME A18.1 Safety Standard for Platform Lifts and Stairway Chairlifts" (ASME A18.1), which provides that these products are to be built and certified to the provisions of the National Electric Code and the Canadian Standards Association (CSA)/ASME standard "CSA B44.1/ASME A17.5 Elevator and Escalator Electrical Equipment" for elevator and escalator equipment.

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 and in 63 FR 3142, and agrees they weigh in favor of 510(k) exemption, as long as certain conditions are met. FDA agrees 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 certain types of routine analysis and nonclinical testing, such as those detailed in certain consensus standards. Therefore, after reviewing the petition, the additional information received on June 19, 2012, and the comment on the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of stairway chair lifts, as long as the conditions for 510(k) exemption listed in this document are met. FDA responded to the petition by letter dated December 3, 2012, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

For clarity, this order: (1) Defines a subset of powered patient transport devices classified under § 890.5150 identified as "powered patient stairway chair lifts," and (2) exempts this subset of devices from premarket notification requirements provided certain conditions are met, which will be codified in this classification regulation. This order does not affect other devices classified under § 890.5150, such as attendant-operated portable stair-climbing chairs (which are different from wheelchairs), which remain subject to premarket notification requirements, and does not change the class of any of the devices classified under this regulation, which all remain in class II. These devices will remain subject to current good manufacturing practices requirements and other general controls under the statute.

## IV. Conditions for Exemption

This final order provides conditions for exemption from premarket notification on appropriate testing and labeling of the device. The following conditions must be met for the device to be 510(k)-exempt: (1) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 "Safety Standard for Platform Lifts and Stairway Chair Lifts") must demonstrate that the safety controls are adequate to prevent a free fall of the chair in the event of a device failure; (2) appropriate analysis and nonclinical testing must demonstrate the ability of the device, including armrests, to withstand the rated load with an appropriate factor of safety; (3) appropriate restraints must be provided to prevent the user from falling from the device (such as that outlined in the currently FDA-recognized edition of ASME A18.1 "Safety Standard for Platform Lifts and Stairway Chair Lifts"); (4) appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of AAMI/ANSI/IEC 60601-1-2, "Medical Electrical Equipment--Part 1-2: General Requirements for Safety--Collateral Standard: Electromagnetic Compatibility--Requirements and Tests," and ASME A18.1 "Safety Standard for Platform Lifts and Stairway Chair Lifts") must validate electromagnetic compatibility and electrical safety; and (5) appropriate analysis and nonclinical testing must demonstrate the resistance of the device upholstery to ignition.

Firms are now exempt from 510(k) requirements for stairway chair lifts as long as they meet these conditions of exemption. Firms must comply with the particular mitigation measures set forth in the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

## V. 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 contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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 890.5150 is revised to read as follows:

§ 890.5150 Powered patient transport.

(a) Powered patient stairway chair lifts--(1) Identification. A powered patient stairway chair lift is a motorized lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.

(2) Classification. Class II. The stairway chair lift 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:

(i) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of American Society of Mechanical Engineers (ASME) A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must demonstrate that the safety controls are adequate to prevent a free fall of the chair in the event of a device failure;

(ii) Appropriate analysis and nonclinical testing must demonstrate the ability of the device, including armrests, to withstand the rated load with an appropriate factor of safety;

(iii) Appropriate restraints must be provided to prevent the user from falling from the device (such as that outlined in the currently FDA-recognized edition of ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”);

(iv) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized editions of AAMI/ANSI/IEC 60601-1-2, “Medical Electrical Equipment--Part 1-2: General Requirements for Safety--Collateral Standard: Electromagnetic Compatibility - Requirements and Tests,” and ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must validate electromagnetic compatibility and electrical safety; and

(v) Appropriate analysis and nonclinical testing must demonstrate the resistance of the device upholstery to ignition.

(b) All other powered patient transport--(1) Identification. A powered patient transport is a motorized device intended for use in mitigating mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs (e.g., attendant-operated portable stair-climbing chairs). This generic type of device does not include motorized three-wheeled vehicles or wheelchairs.

(2) Classification. Class II.

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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