

agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response (ASPR) on other matters related to public health emergency preparedness and response.

**Background:** The June 26, 2012, public meeting will be dedicated to the introduction of two new tasks to the NBSB. The NBSB is being tasked to advise the HHS Secretary on the development of a national public health and healthcare situational awareness strategy and implementation plan. In addition, the NBSB, in collaboration with the Public Health Preparedness and Response—Board of Scientific Counselors, a Centers for Disease Control and Prevention Federal Advisory Committee, is being tasked with identification and evaluation of the anticipated responsibilities of the Strategic National Stockpile for the year 2020. The NBSB continues to review and evaluate the 2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP). Therefore, the Board's deliberations on the PHEMCE SIP task are being conducted in closed sessions in accordance with provisions set forth under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. 552b(c), and with approval by the ASPR. For a full description for the basis for closing the meeting on June 25, 2012, please see the previous meeting notice published at 77 FR 13129 (2012).

**Availability of Materials:** The meeting agenda and materials will be posted on the NBSB Web site at [www.PHE.GOV/NBSB](http://www.PHE.GOV/NBSB) prior to the meeting.

**Procedures for Providing Public Input:** Any member of the public providing oral comments at the meeting must sign-in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to June 21, 2012, and should be sent by email to [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV) with "NBSB Public Comment" as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should email [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV).

Dated: May 25, 2012.

**Nicole Lurie,**

*Assistant Secretary for Preparedness and Response.*

[FR Doc. 2012-13387 Filed 5-31-12; 8:45 am]

**BILLING CODE 4150-37-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HHS gives notice of a determination concerning a petition to add a class of employees from Hangar 481 at Kirtland Air Force Base to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384q. On May 11, 2012, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All employees who worked at Hangar 481, Kirtland Air Force Base, from March 1, 1989 through February 29, 1996.

**FOR FURTHER INFORMATION CONTACT:** Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 1-877-222-7570. Information requests can also be submitted by email to [DCAS@CDC.GOV](mailto:DCAS@CDC.GOV).

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 2012-13378 Filed 5-31-12; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Patents and Inventions; Delegation of Authority

Notice is hereby given that I have delegated to the Director, Division of Laboratory Policy and Practice (DLPP), Laboratory Science Policy and Practice Program Office (LSPPPO), Office of Surveillance, Epidemiology and Laboratory Services (OSELs), Centers for Disease Control and Prevention (CDC), the Deputy Director, DLPP, LSPPPO, OSELs, CDC, and the Chief, Technology Management Branch, DLPP, LSPPPO, OSELs, without authority to redelegate, all authorities to administer

and make decisions regarding the invention and patent program of CDC and the authority to make determinations of rights in inventions and patents in which CDC and the Department have an interest.

This delegation excludes the authority under 35 U.S.C. 203 (March-in Rights) and the authority to submit reports to Congress.

In addition, this delegation excludes those authorities under the Stevenson-Wydler Technology Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation.

The exercise of this authority must be in accordance with applicable laws, regulations, and Office of Government Ethics, U.S. Office of Personnel Management, and DHHS policies and instructions.

This delegation became effective upon date of signature. I hereby affirm and ratify any actions taken that involve the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: May 14, 2012.

**Thomas R. Frieden,**

*Director, Centers for Disease Control and Prevention.*

[FR Doc. 2012-13238 Filed 5-31-12; 8:45 am]

**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

### Medical Devices; Exemption From Premarket Notification: Powered Patient Transport

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for powered patient transport devices commonly known as stairlifts. These devices are used to assist transfers of a mobility impaired person up and down flights of stairs. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit either electronic or written comments by July 2, 2012.

**ADDRESSES:** You may submit comments, identified with the FDA docket number found in brackets in the heading of this document, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527, FAX: 301-847-8122.

#### SUPPLEMENTARY INFORMATION:

##### I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94-295), as amended by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there is information

showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105-115). Section 206 of FDAMA, in part, added a new 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, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device 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. Within 120 days of publication of this document, 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 the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." That guidance is available through the Internet at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf> or by sending an email request to [dsmica@fda.hhs.gov](mailto: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. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Richard Keller, on behalf of Bruno Independent Living Aids, Inc., for powered patient transport devices (commonly known as stairlifts), classified under 21 CFR 890.5150.

##### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-13225 Filed 5-31-12; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-P-0882]

#### Medical Devices; Exemption From Premarket Notification: Wheelchair Elevator

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for wheelchair elevator devices commonly known as inclined platform lifts and vertical platform lifts. These devices are used to provide a means for a disabled person to move a wheelchair from one level to another. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit either electronic or written comments by July 2, 2012.

**ADDRESSES:** You may submit comments, identified with the FDA docket number found in brackets in the heading of this document, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting

comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527, FAX: 301-847-8122.

#### SUPPLEMENTARY INFORMATION:

##### I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred

to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added a new 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, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device 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. Within 120 days of publication of this document, 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.

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