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November 3, 2011

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Class II 510(k) Exemption Petition

Bruno Independent Living Aids, Inc. submits this petition under Section 510(m)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) as amended by Section 206 of the FDA Modernization Act of 1997, to request the Commissioner of Food and Drugs to exempt stairlifts, Class II devices, from the premarket notification requirement of Section 510(k) of the Act.

The information in this petition demonstrates that premarket notification is not necessary to provide assurance of safety and effectiveness of devices classified as stairlifts.

For any written correspondence regarding this petition, please use the following address:

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If there are any questions regarding this petition, please contact me at 262-953-5336, by facsimile at 262-953-5509, or e-mail at www.dick.keller@bruno.com.

Sincerely,

Richard Keller

Richard Keller
Senior Project Leader

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FDA-2011-P-0804

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CLASS II 510(k) EXEMPTION PETITION

November 3, 2011

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Petition to exempt stairlifts (stairway chairlifts) from Premarket Notification Requirements

On behalf of Bruno Independent Living Aids, Inc., the undersigned submits this petition under Section 510(m)(2) of the Federal Food, Drug and Cosmetic Act (the Act) as amended by Section 206 of the FDA Modernization Act of 1997 (FDAMA) to request the commissioner of Food and Drugs to exempt a class II device type, as defined in 21 CFR 860.3(i), from the premarket notification requirements of section 510(k) of the Act.

A. Action requested

In accordance with Section 510(m)(2) of the Act, the petitioner, Bruno Independent Living Aids, Inc., is requesting exemption from the requirement to submit a report under Section 510(k) for a generic type of class II device, commonly known as a stairlift, having the device classification name Powered Patient Transport and regulation number §890.5150. Product Code for the stairlift device is ILK.

B. Statement of grounds

Petitioner believes that the premarket notification requirement is not necessary to assure safety and effectiveness of stairlifts. Although petitioner has been submitting 510(k)s for the stairlift device in various models for more than nineteen years, several other foreign manufacturers have not been doing so, with FDA acceptance. Petitioner believes that the FDA Quality System Regulations and their requirements provide sufficient assurance of safety and effectiveness for stairlifts. In addition, other organizations provide comprehensive standards and oversight to the design and manufacture of stairlifts.

In FDA's *Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff, Section III. Factors FDA May Consider for Exemption*, it states:

In its January 21, 1988 FR notice (63 FR 3142), FDA described the criteria the agency had used to determine which class II device types should be exempt from the premarket notification (510(k)) requirements. The FR notice stated:

> *"In considering whether to exempt class II devices from premarket notification, FDA focused on whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA considered the following factors:*
> *(1) The device does not have a significant history of false or misleading claims or risks associated with inherent characteristics of the device, such as device design or materials;*
> *(2) Characteristics of the device necessary for its safe and effective performance are well established;*
> *(3) Changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before*

causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and

(4) Any changes to the device would not be likely to result in a change in the device's classification.

FDA also considered that even when exempting devices, these devices would still be subject to the limitations as described in (this section) of the document."

The agency believes these factors should also be considered when determining if any additional class II device type(s) should be exempted from 510(k) requirements.

Likewise, a petition by an interested person for an exemption for a class II device type should clearly address the factors described above so the agency and respondents can expeditiously consider whether to concur in the request.

Reviewing the above factors when considering whether premarket notification is necessary to assure safety and effectiveness of the class II stairlift, factors 1 through 4 are addressed below.

(1) The device does not have a significant history of false or misleading claims or risks associated with inherent characteristics of the device, such as device design or materials.

Petitioner is not aware of any significant history of false or misleading claims for the device which is the subject of this petition, either for the devices manufactured by the petitioner or those manufactured by others.

Stairlifts have been commonly used in the United States to assist climbing residential and commercial stairways since the early 20th century. The first FDA 510(k) premarket notification for a stairlift was recorded in 1988 and listed as a Class II medical device. In reviewing the FDA's *Manufacturer and User Facility Device Experience* (MAUDE) and *Medical Device Reporting* (MDR) databases from 01/01/1988 to 10/20/2011, incident reports for death, injury, and malfunction of stairlifts document a remarkable safety history. There have been no reported deaths, 3 injuries, and 2 malfunctions in that time period. This, with an estimated installed base of almost 600,000 stairlifts, is extraordinary.

In the FDA list of *Medical Device Exemptions 510(k) and GMP requirements; class I and II Exempt Devices; Part 890 – Physical Devices*, there are 52 Product Codes. In Table 1, seven product codes from the FDA list are compared with the stairlift code (ILK) which also includes devices other than stairlifts. These seven devices are chosen for comparison because, like the stairlift, they are powered devices which support a human being. When considering safety and efficacy, these reports on the MAUDE and MDR databases contain comparable data on deaths, injuries, (safety) and malfunctions (efficacy) of the devices.

The stairlift, presently a class II device, fares much better than the two class II (510 (k)) exempt devices and compares favorably among the five class I devices as well. It would rank third in the list of eight for safety (least deaths and injuries), and also for efficacy (malfunctions). The databases obviously haven't captured every stairlift malfunction since 1988. However, considering the databases serve a similar sampling of the population over the same time period, that the estimated number of stairlifts greatly exceeds the combined other products shown, and the reported incidents of all types are remarkably low, it demonstrates a high level of safety and efficacy for stairlifts.

TABLE 1						
COMBINED FDA MAUDE & MDR REPORTS 01/01/1988 to 10/20/2011						
PART 890 – PHYSICAL MEDICINE DEVICES – CLASS I & CLASS II EXEMPT						
PRODUCT CODE	DEVICE CLASS	DEVICE NAME	REGULATION NUMBER	DEATH	INJURY	MALFUNCTION
IRR	I	Bars, Parallel, Powered	890.5380	0	0	0
INF	I	Scale, Platform, Wheelchair	890.3940	0	2	0
BXB	I	Exerciser, Powered	890.5380	0	38	50
INQ	I	Table, Powered	890.3760	2	9	3
IOL	I	Treadmill, Powered	890.5380	3	61	98
IKZ	II – 510(k) exempt	Bed, Patient Rotation, Powered	890.5225	12	47	41
IOQ	II – 510(k) exempt	Bed, Flotation Therapy, Powered	890.5170	31	34	79
ILK (stairlifts)	II	Patient Transporter, Powered	890.5150	0	9 (3 stairlifts)	4 (2 stairlifts)

(2) Characteristics of the device necessary for its safe and effective performance are well established. Characteristics of the device necessary for its safe and effective performance are well established as evidenced by the long history of use in residences and commercial buildings. The risks associated with the use of these products is low and is consistent with that of other powered devices which are exempt from premarket notification requirements.

There are other organizations that have rules and standards for the design, manufacture and use of stairlifts. FDA's *Recognized Consensus Standards* lists Recognition Number 16-186, *ASME A18.1-2008, Safety Standard for Platform Lifts and Stairway Chairlifts*. This standard, developed and published by the American Society of Mechanical Engineers under procedures accredited as meeting the criteria of the American National Standards, is intended to serve as the basis for state, municipal, and other jurisdictional authorities in drafting regulations governing the installation, testing, inspection, maintenance, alteration and repair of platform lifts and stairway chairlifts. It is also intended as a standard reference of safety requirements for the guidance of architects, engineers, insurance companies, manufacturers, and contractors, and as a standard of safety practices for owners and management of structures where this equipment is used.

Finally, compliance by the stairlift manufacturer is typically certified by 3rd party bodies (such as FDA, UL, CSA, ETL, etc.) and verified by their listing mark on the stairlift labeling. These bodies partner with

manufacturers to provide safe products to consumers through testing, certification and periodic follow-up audits of the products and manufacturing processes.

(3) Changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.
Changes to the device have largely been evolutionary and are readily detectable because they are communicated to the users by the petitioner. Software in the device and the operator's manual and its updates are specifically designed to communicate changes to the device.

Any changes to the device would not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment because the device has been historically a low risk device, is not used for diagnosis, and it is not used for treatment. Moreover, potential changes to the device will be controlled through the Quality System Regulations (QSRs) as provided in 21 CFR §820 as well as certified compliant to ASME A18.1.

(4) Any changes to the device would not be likely to result in a change in the device's classification.
We do not anticipate any changes in the generic stairlift device design that would change the device classification. Of course, even when these devices are exempted, they would still be subject to the limitations on exemptions.

Limitations on Exemptions
The exemption from the requirement of premarket notification for a generic stairlift applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed stairlifts. Accordingly, a class II stairlift is not exempt if: (1) it has an intended use that is different from the intended use of a legally marketed stairlift; or (2) operates using a different scientific technology than that used by a legally marketed stairlift.

Conclusion
In summary, we believe the stairlift device should be exempt from the class II premarket notification requirements, section 510(k) of the Act. The MDR and MAUDE history databases demonstrate that the stairlift device performs as intended and is safely used as a low risk medical device. The application of FDA's Current Good Manufacturing Practices (CGMP) as well as the General Controls of the Act (Establishment Registration, Device Listing and Labeling), in combination with the Recognized Consensus Standard number 16-186, will assure continued product safety and efficacy.

C. Environmental Impact
Petitioner requests a categorical exclusion from the preparation of an environmental assessment as provided by 21 CFR §25.30(h). If FDA grants petitioner's request to exempt stairlifts from the premarket notification requirement, there will be no increased use of stairlifts nor any other effect on the environment.

D. Economic Impact
Not applicable

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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Senior Project Leader

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