

510(k) SUMMARY

K073513

9.1 Trade/Proprietary Name: Merits E700 Porch Lift

9.2 Common/Usual Name: Vertical Platform Lift

9.3 Classification Name: Wheelchair Elevator

JAN 14 2008

9.4 Comparison to Currently Marketed Devices

The Merits E700 Porch Lift is substantially equivalent to the Bruno Residential Vertical Platform Lift Model VPL-3100 (K061514)

9.5 Device Description

The Merits E700 Porch Lift basically consists of a platform assembly and a driving machine case assembly. The platform assembly vertically moves along a guide rail welded to the driving machine case assembly. The sides of the platform assembly are guarded by sheet steel plates. The lower landing side of the platform is equipped with an automatic folding ramp to not only offer easy access to the platform but also to prevent the mobility device rolling off the edges. The ramp will be automatically folded up as the lift begins to move upward and remain in elevated position until the platform returns to the lower landing. The underside of the platform is equipped with a safety plate to stop the motion when the platform is obstructed in the downward direction. The driving machine case assembly contains all necessary operation systems in the case. The operation of the lift is controlled by the platform operating panel and the call/send controls. These control devices are designed by means of continuous pressure type, which stop the lift immediately when the switch is released. The Merits E700 Porch Lift is using AC power as its power source.

9.6 Intended use

The Merits E700 Porch Lift System is a wheelchair elevator, also commonly known as a vertical platform lift. It is a motorized device intended to mechanically transport an individual with mobility disability, either in a wheelchair device or ambulatory, from one level to another in a private residence.

9.7 Technological Characteristics

Merits E700 Porch Lift is equivalent in functions to the legally marketed predicate device. Although the two lifts are using different driving means for operation, the utilization of chain sprocket by Merits E700 Porch Lift is still reliable to satisfy the driving needs. The application of chain sprocket is well-established and has been extensively used by other legally marketed products. The driving means of chain sprocket has no major technological difference comparing to that of screw. Moreover, the difference of the suspension and braking of the two lifts does not affect their functional effectiveness. Unlike

the screw means adopted by the Bruno's lift, Merits E700 Porch Lift fulfills the functions by means of chains. The technology of chains is mature enough to provide the reliable method to satisfy the specific functional requirements.

9.8 Performance Data

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

9.9 Conclusion

Based on the design, performance specifications, testing, and intended use, the Merits E700 Porch Lift is substantially equivalent to the legally marketed device, Bruno Residential Vertical Platform Lift Model VPL-3100 (K061514)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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China (Taiwan) 40768

JAN 14 2008

Re: K073513
Trade/Device Name: Merits E700 Porch Lift
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: II
Product Code: ING
Dated: December 10, 2007
Received: December 14, 2007

Dear Mr. Chao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number:

Device Name: Merits E700 Porch Lift

Indications For Use:

The Merits E700 Porch Lift System is a wheelchair elevator, also commonly known as a vertical platform lift. It is a motorized device intended to mechanically transport an individual with mobility disability, either in a wheelchair device or ambulatory, from one level to another in a private residence.

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number _____

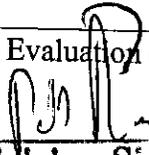
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 16073513