K121561
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OCT 26 2012

510(k) SUMMARY
as required by section 807.92(c)

Submitted by:	ThyssenKrupp Accessibility BV Van Utrechtweg 99 2921 LN Krimpen aan den Ijssel The Netherlands
Contact:	Arnold van der Heiden Mail: avanderheiden@tkacc.nl Tel: +31 180 530900 Fax: +31 180 530901
Date prepared:	05/21/2012
Trade Names:	FLOW2/ SWING
Common Device Name:	Battery Operated Stair Lift for Curved Stairs
Regulation Number	890.5150
Class	II
Product Code:	ILK
Submission	K121561
Predicate Device:	Stair Lift BRUNO Independent Living Aids INC K970927 CFR 890.5150

Promotional Product Description

Flow2 mono rail chairlift brings one person safely and comfortably up and down the stairs. In the meantime one saves ones energy for long outdoor walks, playing with the children or the daily tasks in house.

Flow2 is capable to swivel during the ride up and down the stairs. This unique and patented feature makes that Flow2 chairlift fits most staircases, straight, around corners and even spiral. The angle of the staircase can vary from -70 degrees up to 70 degrees.

The footrest is mounted directly to the chair. This provides a comfortable and ergonomic seating position of the user with less knee flexion.

Flow2 is easy to use by a simple and light folding operation and the intuitive to use joystick control. Features such as anti squeeze, curved armrest and safety belt provide additional safety for the user and other inhabitants of the home.

The design can be adapted to the home decor by the application of a variety of different seat fabrics and colors. Flow2 is the chairlift on the market which combines the best of 2 worlds; capable to fit on the smallest stairs while transporting the user in the most comfortable and safe way.

Intended Use

ThyssenKrupp Accessibilty's Battery Operated Stair Lift is intended to mechanically transport one mobility impaired person in a fold-down seat, up and down curved stairs, indoors.

Product Comparison Tables

Equivalent Technological Characteristics

	Bruno CRE-2110 Electra-Ride	ThyssenKrupp Accessibility Flow2
Standards	ASME 18.1, IEC 60601-1-2:2007	ASME 18.1, IEC 60601-1-2:2007
Application	Straight and Curved stairs	Straight and Curved stairs
Rated Load	400 lb (181 kg) maximum	275 lb (125 kg) maximum
Passengers	1	1
Power	2 pieces 7AH 12 Battery	2 pieces 7AH 12 Battery
Charger	24VDC/ 2A	24VDC/ 2A
Drive	Direct drive worm gear motor	Planetary motor with worm gear
Final Drive	8dp gear rack with spur gear	Lasered rack and pinion
Braking	Dynamic, worm gear, el/mech brake	Dynamic, worm gear, el/mech brake
Call & Send	RF	RF
Supports	Anchored to stair thread	Anchored to stair thread
Angle	50 degrees	70 degrees
Speed	0.13 m/s	0.15 m/s
Track length	15 m	34 m
Location	Designed to contour of stairway	Designed to contour of stairway
Safety devices	Multiple	Multiple
Footrest	Folding type	Folding type
Seat	Folding type	Folding type

Non Equivalent Technological Characteristics

	Bruno CRE-2110 Electra-Ride	ThyssenKrupp Accessibility Flow2
Control	3 position momentary rocker switch	3 position switched RF unit
Construction	Steel welded shape	Bended round steel tube 80mm
Leveling	Mechanically forced	Patented electronic leveling
Swiveling	End of rail	Patented "en route" swiveling

Product Comparison Discussion

Bruno's Electra Ride and ThyssenKrupp Accessibility's Flow2 show substantial equivalence on most standard features and characteristics.

- Both products follow the contour of the stairway by a customer specific design, the only difference in this aspect is that Bruno applies a steel welded shape while ThyssenKrupp uses a bended round steel tube.
- Both products provide levelling of the chair during the ride, the only difference in this aspect is that the Bruno chair is forced mechanically in horizontal position while ThyssenKrupp applies a patented multiple sensor controlled electronic levelling system
- Both products provide swivelling of the chair for easy getting on and off the chair, the only difference in this aspect is that ThyssenKrupp provides patented "en route" swivelling to allow installation at narrow staircases

ThyssenKrupp Accessibility's Flow2 mainly shows non equivalence with Bruno's Electra Ride on electronic control. The system – electronics included – is certified by ETL and Lift Institute as stated by the ETL Listing Report and Lift Institute Type Approval, based on international stair lift standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2012

Thyssenkrupp Accessibility B.V.
% Mr. Arnold Heiden
Technical Advisor
Van Utrechtweg 99
Krimpen aan den Ijssel
Zuid-Holland, Netherlands 2921 LN

Re: K121561
Trade/Device Name: FLOW2
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: Class II
Product Code: ILK
Dated: October 23, 2012
Received: October 25, 2012

Dear Mr. Heiden:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K121561

Device Name: FLOW2

Indications for Use:

ThyssenKrupp Accessibility's Battery Operated Stair Lift FLOW2 is intended to mechanically transport one mobility impaired person in a fold-down seat, up and down curved stairs, indoors.

Prescription Use (Part 21 CFR 801 Subpart D)	NO	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	YES

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121561