K090856

510 (K) SUMMARY

(In accordance with 21 CFR 807.92)

MAY 27 2009

Submitted by: ThyssenKrupp Ceteco S.r.l.
Via S. Cannizzaro n° 2
56121 PISA (PI) - ITALY

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Date prepared: 23 March 2009

Trade Name: JOURNEY

Common Device Name: Wheelchair Elevator or Inclined Platform Lift

Predicate device: Garaventa Stairlilft GSL Inclined Platform Lift
K981486
21CFR 890.3930
Classification code: ING

Product description:

The JOURNEY consists of a motorized main-frame with a platform, moving on a proper rail through a pinion on a rack placed at the bottom of the slide guide; It moves between fixed floors in a public or private dwelling; it is an unenclosed Inclined Platformlift. The JOURNEY is designed to carry a wheelchair and its occupant or a person with impaired mobility seated on a folding seat.

There are currently two different models designed to address different kind of staircase.

- The JOURNEY (technically called RPSP) designed strictly for straight stairways.
- The JOURNEY CUBIC (technically called TP or SUPRA) designed for straight and turning stairways.

Each of the two models is accessible via four types of platform (special size are available under request); these platforms are raised manually or automatically; the ramps are raided automatically (manually in emergency cases).
The JOURNEY, as rail, uses one guide, dimensions roughly 400 mm x 65 mm; the guide is made in extruded aluminium profile (TK Ceteco drawing) and anodised.
The JOURNEY CUBIC, as rail, uses two parallel guides, custom-bended according to the stairway, dimensions roughly 80mm x 40mm each; the guide is made in extruded aluminium profile (TK Ceteco drawing) and powder coated painted.

The guide follows the average of staircase and is supported by specific stanchions, anchors on the steps and/or to the wall.
The JOURNEY is equipped with an "Over-speed Governor and Safety Gear" that it is directly and mechanically fixed on the "system drive". The OSG is operated directly by a speed limiter device with input inertia due to the increased speed; in case of failure of the traction system, the insertion of the device causes the arrest of the main electric motor and ensures a "progressive mechanical arrest" of the platform lift.
The JOURNEY is equipped with "Hold to run Buttons" and with an emergency stop button.
The JOURNEY is also provided the following safety devices:

- anti-scissor system and shockproof in motion towards' high on both the body and the platform;
- anti-crashing system in motion down under the bottom of the platform and on the bottom of the body;
- anti-cushioning system in motion down on the edge of the platform and the body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Tyssenkrupp Ceteco Srl
% Mr. Fabrizio Fedele
Via, S. Cannizzaro, 2
Pisa
Italy 56121

Re: K090856
Trade/Device Name: Inclined Platform-Lift "Journey"
Regulation Number: 21 CFR 890.3930
Regulation Names: Wheelchair elevator
Regulatory Class: II
Product Code: ING
Dated: April 28, 2009
Received: May 7, 2009

Dear Mr. Fedel:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K090856

Device Name: Inclined Platform-Lift "JOURNEY"

Indications for Use:

The Inclined Platform-Lift "JOURNEY" is intended to mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility either in indoors or outdoors.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(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

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