K110495

MAY 2 0 2011

510(k)Summary

SANO Transportgerate GmbH
LIKFTKAR PT™, Elevator Wheelchair
PRODUCT CODE **ING**
Regulation Name **Wheelchair Elevator Sec. 890.3930**
Class II

Submitter's Information

SANO Transportgeraete Gmbh
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Dated Prepared: 1/20/11

Name of Device and Sponsor
LIFTKAR PT™ Product of SANO

Common Name
Elevator, Wheelchair

Classification Name
Class II General Controls and Special Controls. Elevator Wheelchair

Predicate Device
Scalamobil (K920105)

Intended Use
The intended use of the LIFTKAR PT™ is to transport a wheelchair user or a person needing assistance up or down stairs by means of a battery powered, mobile lifting device. LIFTKAR PT is operated by an attendant and is used in residential and public facilities indoors and outside.

Device Description

The LIFTKAR PT™ ADAPT is an attendant operated, battery powered lifting device that transports manual wheelchairs up or down stairs. The LIFTKAR PT is designed for indoor and outdoor use allowing mobility for the person needing assistance.

A portable stair-climber LIFTKAR PT can be dismantled into three parts, the climber unit, the battery pack and the handle. All parts are lightweight and easy to stow away.

Substantial Equivalence

The LIFTKAR PT™ ADAPT is substantially equivalent to the Scalamobil K920105.

The predicate device Scalamobil manufactured by Ulrich Alber was evaluated by FDA under (k920105). Like the LIFTKAR PT the Scalamobil is a fully portable stair-climbing transporter designed to permit a manual wheelchair to go up or down stairs with an attendant operating the lifting device. The benefit of an attendant operated product is they must be certified to operate these devices and they are required to inspect the product and the stairs, for safety and effectiveness, each time the device is used.

Both the LIFTKAR PT™ and the predicate device are portable wheelchair transporters that attach to wheelchairs, safely and comfortably with a minimum of backward and forward tilting. Both attach to a wheelchair via a clamp mechanism. And both use a lifting device to go up and down stairs, with the use of braked wheels.

The wheelchair is fitted with brackets, that may be attached and removed as necessary.

To attach to the wheelchair the climbing unit is simply wheeled under the chair, so that the lower bolts of the power unit lock into the lower hook brackets already mounted on the wheelchair. The attendant lifts the upper bolt component, by pressing the UP switch on the handlebar and it locks into the clamps. The attendant then inserts the two locking pins into the clamp to secure the product to the wheelchair. The quick release wheels of the wheelchair are removed and placed back on when stairs are completed.

The stair-climbing principles are identical- one set of wheels secures the wheelchair on one stair and another set of wheels reach the next step. Both use a chain mechanism.

LIFTKAR PT™ ADAPT as well as Scalamobil carry an independent power source, making it a portable device, lightweight and compact. Both products break down into 3 parts, handle, battery and climbing device. Both way approximately the same and both can carry approximately the same weights.

Both the LIFTKAR PT™ ADAPT and the Scalamobil have models that are simply connected accessories to the product.

Product Comparison

PT-Adapt 160		Scalamobil
Minimum wheelchair width	12.6 inches	11 inches
***Weight** (total):*	54.34 lbs	54 lbs
Safe Workload (incl. wheelchair)	352 lbs	308 lbs
Overall height:	44.49 inches	44 inches
Overall width:	18.98 inches	19 inches
Stair Landing minimum:	*35.4 x 35.4 inches*	*36 x 36 inches*
Maximum Stair Height	8.25 inches	10 inches w/extension
Battery	Sealed lead gel	Sealed lead gel
Capacity with fully charged battery	300 steps	300 steps
Battery capacity	5 ah	3.3 ah
Nominal output voltage of charge	24V	24 V
Charging current	1 amp	1 amp
Three main components: Handle, lifting device, battery	Same	Same

Performance Data

The LIFTKAR PT™ ADAPT was tested by BERLIN CERT Pruf und Zertifizierstelle for Medizinnprodukte GmbH an der Technischen Universitat Berlin, TEST Reports in Section: 11.7-32

LIFTKAR PT ADAPT conforms with the following standards :

ISO 7176-23:2002 Requirements and Test Methods for attendant - operated stair climbing devices
ISO 7176-1:1999 Wheelchairs Determination of static stability
ISO 7176-5:2008 Wheelchairs Determination of overall dimensions, mass and maneuvering space
ISO 7176-6:2001 Wheelchairs Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-9:2001 Wheelchairs climatic tests for electric wheelchairs

ISO 7176-14:2008 Wheelchairs Power and control systems for electrically powered wheelchairs and scooters-Requirements and test methods
ISO 7176-21:2009 Wheelchairs Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-11:1992 Wheelchairs-Part 11 Test Dummies (Physical Medicine) Date of Standard 1992
ISO 7176-15:1996 Wheelchairs Requirements for Information disclosure, documentation and labeling.
ISO 7176-8:1998 Wheelchairs Requirements and test methods for static impact and fatigue strength
EN 12184:1999 Electrically Powered Wheelchair, scooters and their chargers.

The performance Data results of the testing confirm that the device meets specifications for performance criteria and the functions it was intended for. And is substantially equivalent to the predicate device.

Conclusion

Based on the design, performance specifications, testing, and intended use, the LIFTKAR PT™ is substantially equivalent to the legally marketed device, Scalamobil (k920105).

Since the device is essentially the same as the elevator, wheelchair stair-climbing device already marketed, (Scalamobil K920105), no effect on the safety and or effectiveness of the device is expected.

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

MAY 2 0 2011

Sano Transportgeraete GmbH
% Ingegnoso Technologies, LLC
Ms. Jeanine A. Carroccio
4028 Belleaire Lane
Downers Grove, Illinois 60515

Re: K110495
Trade/Device Name: LIFTKAR PT™
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: Class II
Product Code: ING
Dated: January 20, 2011
Received: February 22, 2011

Dear Ms. Carroccio:

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

INDICATION FOR USE

510(k) Number:

Device Name: LIFTKAR PT™

Indications For Use:

The LIFTKAR PT™ Is a wheelchair, elevator commonly known as an easy method of transporting wheelchair users or disabled persons, up and down stairs safely. This is done with a lifting mechanism. It is a battery powered attendant operated mobile stair-climber. LIFTKAR PT™ can be used on any stairs indoors or outside.

Prescription Use _____ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110495