OCT 5 - 2004

K042535

Ulrich Alber GmbH + Co. KG
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510(k) summary

ADVENTURE

Identification of Legally Marketed Devices:

Ranger RWD

1. Applicant: Invacare Corp.
2. Manufacturer: Invacare Corp.
3. Device Name: Ranger RWD
4. 510(k)-Number K993413
5. Decision Date: 12/15/1999

Trax

1. Applicant: Permobil A.B.
2. Manufacturer: Permobil A.B.
3. Device Name: Trax
4. 510(k)-Number K993413
5. Decision Date: 12/18/2000

D. Description of the device

The Adventure A10 wheelchair is a lightweight wheelchair with full spring suspension and extremely good outdoor driving characteristics which can also be used indoors without any problems, due to its maneuverability.

All components are made of non-corrosive materials or have an anti-corrosive surface.

The housing for electronic components and all plug connections fulfill the IPX4 degree of protection. The permitted operating temperature lies between –25°C and +50°C.

In addition to the comfort offered on normal asphalted streets, roads and paths, the A10 also offers a high degree of driving comfort on cobbled streets and, in particular, on field and forest paths and on level meadows. This is realized through its chassis with full spring suspension, longitudinal steering wheels and individual wheel suspension elements.
Spring travel is 52 mm.

Obstacles up to a height of 120 mm can be negotiated with the aid of a curb climber included in the accessories.

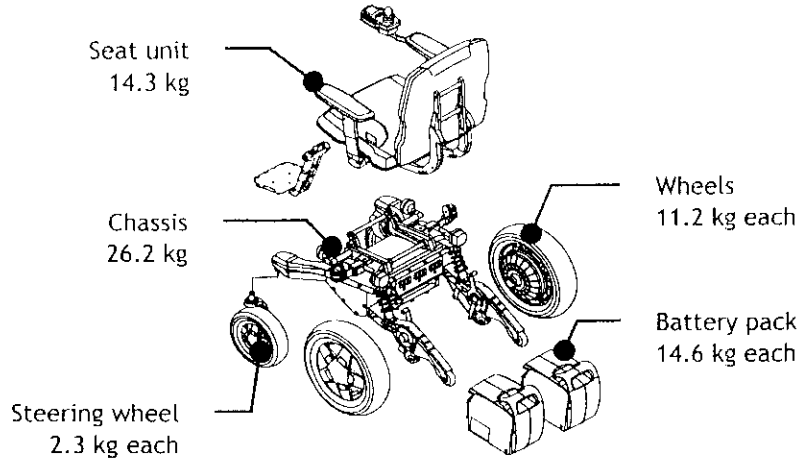
The tires are designed to achieve good rolling characteristics and noise-free operation on smooth surfaces, both indoors and outdoors. The integrated cleat tread provides the required traction in off-road use.

The tilt supports secure the vehicle against tilting backwards when negotiating obstacles and slopes. The Adventure can be raised on the drive wheels with the integrated jack-up mechanism to facilitate their removable and refitting.

The Adventure can be rapidly and simply dismantled into 8 individual components without tools or aids, thanks to the modular construction. Contact is established automatically during this with the drives and battery packs.

The modular construction of the Adventure means it can also be transported easily in smaller vehicles. Defective components can be replaced quickly in the event of a breakdown, meaning that long periods of disuse are avoided and there is no longer any need to send the entire wheelchair in for repairs.

The logical lightweight construction means that the max. empty weight is 96.7 kg (without accessories). The weight of individual removable components is derived as follows:



The max. permissible occupant weight is 140 kg. The permissible overall weight is 255 kg. Slopes and gradients up to 18% and sloping ground up to 12% can be safely traversed, thanks to the optimally positioned center of gravity of the Adventure.

The compact dimensions of the Adventure, with an overall length of 1100 - 1300 mm (depending on the setting of the seat angle and leg supports), a max. width of 680 mm and a turning radius of 950mm enable its easily handling, even indoors. An option exists for switching the control on the control panel to indoor mode, enabling better control of the vehicle in confined spaces.

The removable seat is available in standard and function seat versions.
The standard seat is equipped with washable, non-removable seat padding and has limited adjustment functions.

The function seat version is available with standard or comfort padding, each of which is removable and washable.
In contrast to the standard seat, the function seat has continuous adjusting options for both the back and leg supports. The seat width, depth and back height can also be varied.
The armrests are removable or can be simply pivoted to the rear (to facilitate movement of the occupant).

The Adventure is equipped with a parking brake which can be actuated by the driver. The Adventure can be pushed by an accompanying person when the parking brake is released and the system deactivated.

The various driving parameters which can be adapted to suit the occupant's disability can be edited directly on the control panel without an additional external programming unit.

E. Intendend use statement

A wheelchair can be provided as a result of medical indication where walking is no longer possible or the ability to walk is severely restricted through:

- paralysis
- loss of a limb or limbs
- defects/deformation of a limb or limbs
- contractures of the joints
- other illnesses

The intended use of the wheelchair is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair

F. Technological Characteristics summary

The Adventure is substantially equivalent to Invacare´s Ranger RWD, cleared on 12-15-1999 as K993413.

The Adventure is also substantially equivalent to Permobil´s Trax, cleared on 12-18-2000 as K993413.

Both substantially equivalent wheelchairs had to be tested on the same international standards for wheelchairs and both are listed by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2004

Ulrich Alber GMBH
c/o Mr. Stefan Preiss
TUV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K042535
Trade/Device Name: Adventure A10
Regulation Number: 21CFR 890. 3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 14, 2004
Received: September 20, 2004

Dear Mr. Preiss:

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.

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
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 (if known): K042535

Device Name: Adventure A10

Indications For Use:

A wheelchair can be provided as a result of medical indication where walking is no longer possible or the ability to walk is severely restricted through:

- paralysis
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Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K042535