K060936

ParaBaseTec GmbH · Hauptstrasse 3c · 37434 Bodensee

510(k) Summary

AUG - 7 2006

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	ParaBaseTec, GmbH
2.	*Address:*	Haupstrasse 3C Bodensee, Germany
3.	*Telephone:*	49-5507-979-9108
4.	*Contact Person:*	Anthony Netto
5.	*Date Prepared:*	March 28, 2006
6.	*Registration Number:*	In Process

B. Device

1.	*Name:*	ParaGolfer
2.	*Trade Name:*	ParaGolfer
3.	*Common Name:*	Standup Wheelchair
4.	*Classification Name:*	Wheelchair, Standup
5.	*Product Code:*	IPL
6.	*Class:*	II
7.	*Regulation Number:*	890.3900

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C. Identification of Legally Marketed Devices

1. *Name:* comfort II
2. *K Number:* K051387
3. *Date Cleared:* June 10, 2005

D. Description of the Device

The ParaGolfer Standup Wheelchair is a front wheel drive powered standup wheelchair, manufactured in Germany at production facilities of OTTO BOCK HealthCare.
The ParaGolfer Standup Wheelchair has a "U" frame, controlled by a Curtis Instruments Controller, electronic regenerative disc brakes and Micro Motor.

E. Intended Use Statement

The ParaGolfer Standup Wheelchair is a front wheel drive powered standup wheelchair with an air-filled rear wheel for active users. These wheelchairs provide mobility to physically challenged persons. The wheelchair can be moved by the user operating the Curtis Instruments MC-2 Control System that is connected to the Micro Motor. The wheelchair is steered by different rotation of the rear wheel. It features a servo-steering with release mechanism. The ParaGolfer has an integrated stand-up function. When actuating the standup function via the control console, a motorized lifting device moves the seat of the ParaGolfer from a horizontal to vertical position. At the same time the angles on the backrest and footrest adapt in such a way that the user is brought to an upright posture.

F. Technological Characteristics Summary

The ParaGolfer Wheelchair is substantially equivalent to the LEVO AG comfort II Wheelchair, cleared on June 10, 2005 as K051387.

Each wheelchair is a standup, powered wheelchair for the active user, with a rigid frame and similar characteristics.

E. Contact

Contact Person: Anthony Netto

Telephone: 49-5507-979-9108

Facsimile: 49-55-7-979-144

F. FDA Registration

Registration No.: In Process

Owner/Operator No.: In Process

G. Name/Address of Assembler

Assembler Company: OTTO BOCK HealthCare GmbH

Street Address: Lindenstrasse 13

City: Konigsee

Country: Germany

Postal Code: D-07426

H. Contact

Contact Person: Tom Wessel

Telephone: 763-489-5134

Facsimile: 763-519-9017

I. FDA Registration

Registration Number: 9681725

Owner/Operator Number: 8010097

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The ParaGolfer was tested by TÜV Product Service to the following standards:

- EN 12184
- ISO 7176 – Series, including 7176-20
- ANSI/RESNA WC Vol. 2 Section 21 Amendments 1998 for EMC

with the conclusion that "the test sample fulfills the requirements."

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2006

ParaBaseTec, GmbH
% W F Jackson Associates, Ltd.
Mr. William Jackson
Regulatory Consultant
2247 Jennifer Lane
St. Paul, Minnesota 55109-2851

Re: K060936
Trade/Device Name: ParaGolfer Standup Powered Wheelchair
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: II
Product Code: IPL
Dated: June 30, 2006
Received: July 6, 2006

Dear Mr. Kramer:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehrig
for

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: *To be determined*

Device Name: ParaGolfer Standup Powered Wheelchair

Indications for Use:

- Any individual who needs a power wheelchair and can not stand up on their own such as people with Paraplegia, Spina Bifida, Cerebral Paresis, Multiple Sclerosis, Muscular Dystrophy, and Polio.
- Any individual to take part in sports activities requiring an upright position.

PRESCRIPTION USE _____ AND/OR OVER-THE-COUNTER USE __X__
(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)

Barbara Bruehs for MKM

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

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