Otto Bock
HEALTH CARE

K041208

OCT 1 - 2004

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	OTTO BOCK HealthCare LP
2.	*Address:*	Two Carlson Parkway N., Suite 100 Minneapolis, MN 55447-4467
3.	*Telephone:*	763-489-5105
4.	*Contact Person:*	Bob Clarke
5.	*Date Prepared:*	April 12, 2004
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	B-500 Powered Wheelchair
2.	*Trade Name:*	B-500 Powered Wheelchair
3.	*Common Name:*	Powered wheelchair
4.	*Classification Name:*	Powered wheelchair
5.	*Product Code:*	ITI
6.	*Class:*	II
7.	*Regulation Number:*	890.3860

QUALITY FOR LIFE

North American Headquarters
Two Carlson Parkway N., Suite
Minneapolis, MN 55447-4467
Phone 1.800.328.4058
Fax 1.800.655.4963

Customer Support & Distribution Center
14630 28th Avenue North
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Phone 1.800.328.4058
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Technical Center
14800 28th Avenue North, Suite
Minneapolis, MN 55447-4873
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Florida Area Fabrication Center
755 Clay Street
Winter Park, FL 32789
Phone 1.800.354.5418
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Ohio Area Fabrication Center
84 Westpark Road
Centerville, OH 45459
Phone 1.937.432.0082
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Utah Design & Manufacturing Center
3820 W. Great Lakes Drive
Salt Lake City, UT 84120-720
Phone 1.801.956.2400
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820 Sundial Drive
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Phone 1.800.688.4832
Fax 1.320.251.0110

Customer Satisfaction Hotline
1.877.OBSOLVE
1.877.627.6583

www.ottobockus.com

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C. Identification of Legally Marketed Devices

1. *Name:* P200
2. *K Number:* K924278
3. *Date Cleared:* March 28, 1994

D. Description of the Device

The B-500 Powered Wheelchair is a rear wheel drive powered wheelchair, manufactured in Germany at production facilities of OTTO BOCK HealthCare. The B-500 has an "H" frame, controlled by a P&G Controller, electronic regenerative disc brakes and Micro Motor.

E. Intended Use Statement

The B-500 is rear wheel drive powered wheelchair for active users. These wheelchairs provide mobility to physically challenged persons. The wheelchair can be moved by the user operating the remote control. The wheelchair can also be pushed by an assistant grasping the handles attached to the back rest.

F. Technological Characteristics Summary

The B-500 Wheelchair is substantially equivalent to the Quickie Designs P200 Wheelchair, cleared on March 28, 1994 as K924278.

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

The B-500 was tested by TÜV Product Service to the following standards:

- EN 12184
- ISO 7176 – Series
- ANSI/RESNA WA 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

OCT 1 - 2004

Otto Bock HealthCare, LP
C/o William Jackson
W.F. Jackson Associates, Limited
2247 Jennifer Lane
St. Paul, Minnesota 55109-2851

Re: K041208
Trade/Device Name: B-500 Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 18, 2004
Received: September 22, 2004

Dear Mr. Jackson:

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 Mark N Melkerson

Celia M. Witten, PhD, MD
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): K041208

Device Name: B-500 Powered Wheelchair

Indications for Use:

- Provide mobility to persons physically challenged and limited to sitting position.

Prescription Use ___ AND/OR Over-The-Counter Use _X_
(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)

for Mark N Milhoan

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

510(k) Number K041208