



HEALTH CARE

K 041211

OCT 1 - 2004

510(k) Summary

QUALITY FOR LIFE

510(k) SUMMARY  
of  
SAFETY and EFFECTIVENESS

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

**A. General Information**

**Customer Support &  
Distribution Center**  
14630 28<sup>th</sup> Avenue North  
Minneapolis, MN 55447-4821  
Phone 1.800.328.4058  
Fax 1.800.962.2549

- 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

**Technical Center**  
14800 28<sup>th</sup> Avenue North, Suite  
Minneapolis, MN 55447-4873  
Phone 1.800.795.8846  
Fax 1.800.810.7994

**Florida Area Fabrication Center**  
755 Clay Street  
Winter Park, FL 32789  
Phone 1.800.354.5418  
Fax 1.407.599.7999

**B. Device**

**Ohio Area Fabrication Center**  
84 Westpark Road  
Centerville, OH 45459  
Phone 1.937.432.0082  
Fax 1.937.432.0087

- 1. *Name:* C-1000 Powered Wheelchair
- 2. *Trade Name:* C-1000 Powered Wheelchair
- 3. *Common Name:* Powered wheelchair
- 4. *Classification Name:* Powered wheelchair
- 5. *Product Code:* ITI
- 6. *Class:* II
- 7. *Regulation Number:* 890.3860

**Utah Design &  
Manufacturing Center**  
3820 W. Great Lakes Drive  
Salt Lake City, UT 84120-7205  
Phone 1.801.956.2400  
Fax 1.801.956.2401

**Minnesota Design &  
Manufacturing Center**  
820 Sundial Drive  
Waite Park, MN 56387  
Phone 1.800.688.4832  
Fax 1.320.251.0110

**Customer Satisfaction Hotline**  
1.877.OBSOLVE  
1.877.627.6583

www.ottobockus.com

**C. Identification of Legally Marketed Devices**

1. *Name:* Chairman
2. *K Number:* K960951
3. *Date Cleared:* April 30, 1997

**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

**D. Description of the Device**

The C-1000 Powered Wheelchair is a front wheel drive powered wheelchair, manufactured in Germany at production facilities of OTTO BOCK HealthCare. The C-1000 has an "H" frame, controlled by a Curtis Instruments MC-2, electronic regenerative disc brakes and Micro Motor.

**Customer Support & Distribution Center**  
14630 28<sup>th</sup> Avenue North  
Minneapolis, MN 55447-4821  
Phone 1.800.328.4058  
Fax 1.800.962.2549

**Technical Center**  
14800 28<sup>th</sup> Avenue North, Suite  
Minneapolis, MN 55447-4873  
Phone 1.800.795.8846  
Fax 1.800.810.7994

**E. Intended Use Statement**

The C-1000 is front 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.

**Florida Area Fabrication Center**  
755 Clay Street  
Winter Park, FL 32789  
Phone 1.800.354.5418  
Fax 1.407.599.7999

**Ohio Area Fabrication Center**  
84 Westpark Road  
Centerville, OH 45459  
Phone 1.937.432.0082  
Fax 1.937.432.0087

**F. Technological Characteristics Summary**

The C-1000 Wheelchair is substantially equivalent to the Permobil AB Chairman Wheelchair, cleared on April 30, 1997 as K960951.

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

The C-1000 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."

**Utah Design & Manufacturing Center**  
3820 W. Great Lakes Drive  
Salt Lake City, UT 84120-720  
Phone 1.801.956.2400  
Fax 1.801.956.2401

**Minnesota Design & Manufacturing Center**  
820 Sundial Drive  
Waite Park, MN 56387  
Phone 1.800.688.4832  
Fax 1.320.251.0110

**Customer Satisfaction Hotline**  
1.877.OBSOLVE  
1.877.627.6583



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 1 - 2004

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

Re: K041211

Trade/Device Name: C-1000 Powered Wheelchair  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered Wheelchair  
Regulatory Class: 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.

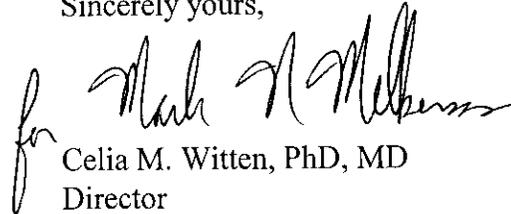
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. William Jackson

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,

A handwritten signature in black ink, appearing to read "Mark A. Melanson". To the left of the signature is a small, stylized "for" written vertically.

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): K041211

**Device Name:** C-1000 Powered Wheelchair

**Indications for Use:**

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

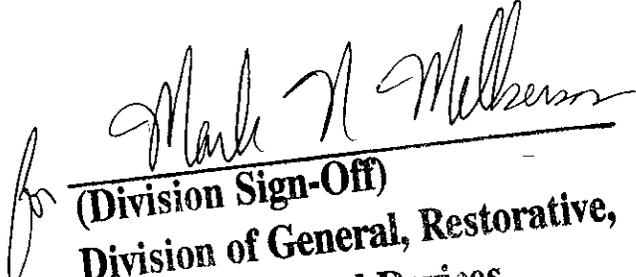
Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(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 General, Restorative,  
and Neurological Devices**

**510(k) Number** K041211