K103477

ORIGINAL, TRADITIONAL 510(K) NOTIFICATION
PERMOBIL POWERED WHEELCHAIR: **M300/M400**

MAR - 3 2011

Attachment 11

510(k) Summary

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Contact Person: Jan Åström
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Date Prepared: October, 2010

Device name: M300 & M400

Classification Name:
Powered wheelchair

Predicate Devices:
C350 (K071650) manufactured by Permobil AB.

Intended use:
The intended use of the M300 & M400 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Description of device:
M300 & M400 Powered Wheelchair is battery powered, center wheel motor driven and is controlled by the PG power wheelchair VR-2 90 amp or R-net 120 amp controller.
The user interface is a joystick.
M300 & M400 is powered by two 12VDC 60Ah, Group M34 batteries, approximate driving range on fully charged batteries is up to 25km (15,5 miles), depending on use and the terrain the chair is driven on.
The chair frame is a rived nut and welded steel construction and includes two center drive wheels with drive units (motor, gear, brake), batteries and front and rear pivoting casters.
Depending on users needs, the joystick motor control is mounted to the left or right armrest.
When the user activates the joystick, the controller receives a signal to release the brakes.
With the brakes released, the chair is allowed to move in the direction the joystick is actuated.
When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user stop by letting go of the joystick.

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Performance Data

In all instances, the M300 & M400 functioned as intended.

Substantial Equivalence

The M300 & M400 is substantially equivalent to the C350 (#K071650). The M300 & M400 has the same intended uses and similar indications, technological characteristics and principles of operation. The minor technological differences between the C350 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the M300 & M400 is as safe and effective as the C350. Thus, the M300 & M400 is substantially equivalent.

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

Permobil AB
% Jan Astrom
Box 120
S-861 23 Timra, Sweden

MAR - 3 2011

Re: K103477
Trade/Device Name: M300 and M400
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 10, 2011
Received: January 19, 2011

Dear Jan Astrom:

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,

for

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 Not assigned at the writing of this submission.

Device name: **M300 & M400**

Indication for Use

The intended use of the CM300/400 series of the powered wheelchair is to provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.

Prescription use ___X___ **or** **Over the counter use** _____

(Part 21 CFR 801 Subpart D) **(Part 21 CFR 807 Subpart C)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103477