K123290

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

APR 17 2013

Attachment 11

510(k) Summary

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Contact Person: Jan Åström
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Date Prepared: April 2013

Device name: M300 & M400

Classification Name:
Powered wheelchair (21 CFR 890.3860, Product Code ITI)

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

Testing was performed in accordance with the following standards:

- ISO 7176-9:2001 Wheelchairs - Part 9: Climatic tests for electrical wheelchairs
- ISO 7176-11:1992 Wheelchairs - Part 11: Test Dummies
- ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- ISO 7176-14 2008 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters. Requirements and test methods
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility
- RESNA WC-1:2009 Wheelchairs – Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters)
- RESNA WC-2:2009 Wheelchairs – Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems

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

Substantial Equivalence

The Permobil M300 and M400 wheelchairs are substantially equivalent to the cleared predicate device, the Permobil C350, as outlined in the following table:

Characteristic	Permobil M300 & M400	Permobil C350 (K071650)
Intended use	To provide indoor and outdoor mobility to persons restricted to a sitting position that are capable of operating a powered wheelchair	To provide indoor and outdoor mobility to persons restricted to a sitting position that are capable of operating a powered wheelchair
Type of base	Mid wheel driven	Rear wheel driven
Caster wheel dimension	200x50	210x65
Drive wheel dimension	3.00-8	3.00-8
Adjustable Anti-Tip Wheels	The front and rear castor wheels function as Anti-tip devices.	Anti tip device mounted in the rear, R100/32-2-v/4"
Over all dimension, l/w/h in	1256/620/1260 (49 1/2"/ 24 1/2"/49 1/2")	1065/625/1110 (42"/24 Y2'/43 'h")
Weight incl. batteries	155kg (342 lbs)(incl. PS-Seat and seat elevator, seat tilt)	142 kg (313 lbs)(incl. PS-Seat and seat elevator)
Weight bearing capacity	136 kg (300 lb)	136 kg (300 lb)
Maximum speed	Up to 12 km/h (7,5 mph)	Up to 10 km/h (6,2 mph)
Brake system	Multiple brake system: 1. Electronic braking by drive motors. 2. Magnetic parking brakes that automatically stops the chair in case of power failure.	Multiple brake system: 1. Electronic braking by drive motors. 2. Magnetic parking brakes that automatically stops the chair in case of power failure.
Ground clearance/Obstacle-climbing	77mm/70mm (372 3/4")	70 mm/60 mm (2 3/4" /2 1/3")
Turning Radius	800mm (31,5")	954 mm (37")
Driving range	Up to 25 km (16 miles)	Up to 25 km (16 miles)

The M300 & M400 are 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 are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

Permobil
C/O Michael Heyl
Hogan Lovells USP
Columbia Square
555 Thirteenth Street, NW
Washington DC, 20004

Re: K123290
Trade/Device Name: M300/M400 powered wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 14, 2012
Received: March 14, 2013

Dear Mr. Heyl:

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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123290

Device Name: M300 & M400

Indications For Use:

The intended use of the M300 & M400 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 _____ 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)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _K123290_____