K081964

ORIGINAL, TRADITIONAL 510(K) NOTIFICATION
PERMOBIL POWERED WHEELCHAIR: **K450**

Attachment 11

510(k) Summary

JUL 29 2008

Submitter Permobil AB
Box 120
S-861 23 Timrå
Sweden

Phone: +46 60 595900
Facsimile: +46 60 575250

Contact Person: Jan Åström
e-mail address: jan.astrom@permobil.se

Date Prepared: July, 2008

Device name: K450

Classification Name:
Powered wheelchair

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

Intended use:
The intended use of the K450 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:
K450 Powered Wheelchair is battery powered, rear wheel motor driven and is controlled by the PG power wheelchair R-net PM120 amp controller.
The user interface is a joystick.
The K450 is powered by two 12VDC 60Ah, Group M34 batteries, approximate driving range on fully charged batteries is up to 26,9 km (16,7 miles), depending on use and the terrain the chair is driven on.
The chair frame is a welded steel construction and includes two rear drive wheels with drive units (motor, gear, brake), batteries and front 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.

ORIGINAL, TRADITIONAL 510(K) NOTIFICATION
PERMOBIL POWERED WHEELCHAIR: **K450**

Performance Data

In all instances, the K450 functioned as intended.

Substantial Equivalence

The K450 is substantially equivalent to the C350(K071650). The K450 has the same intended uses and similar indications, technological characteristics and principles of operation. The minor technological differences between the K450 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the K450 is as safe and effective as the C350. Thus, the K450 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2008

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

Re: K081964
Trade/Device Name: K450 Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 10, 2008
Received: July 10, 2008

Dear Ms. 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORIGINAL, TRADITIONAL 510(K) NOTIFICATION
PERMOBIL POWERED WHEELCHAIR: **K450**

INDICATION FOR USE

510(k) number Not assigned at the writing of this submission.

Device name: **K450**

Indication for Use

The intended use of the K450 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 General, Restorative,
and Neurological Devices

510(k) Number K081969