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K991658

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

PERMOBIL POWERED WHEELCHAIR 1280

Submitter Permobil AB
Box 120
S-861 23 Timrå
Sweden

Phone +46 60 59 59 00
Fax +46 60 57 52 50

Contact person Bengt Persson
E-mail address bengt.persson@permobil.se

Date Prepared May 10 1999

Device name Powered wheelchair 1280

Classification name
Powered wheelchair

Identification of predicate devices
Permobil Chairman L/CS 8 (K960951)
G-424 power wheelchair (K983677)

Intended use

The intended use of Permobil powered wheelchair 1280 is to provide indoor and outdoor mobility to persons restricted to a sitting position.

Description of the device

The Permobil powered wheelchair 1280 is front wheel driven, battery powered, motor driven and is controlled by the Penny & Giles compact powered wheelchair controller Pilot +. The joystick is integrated in the controller.
The wheelchair is powered by two 12V 73 Ah batteries.
Theoretical driving range on the fully charged batteries is 35 km.
The wheelchair consists of two basic sub-sections. These are the base with motor controller and the body supporting system. In this submission, only the design changes made to base is included. The base is of welded steel construction and includes the base frame, front drive wheels with drive unit (motor/gear/brakes), batteries and pivoting rear casters. The motor controller is mounted to the left or right armrest, depending on user needs.
The motor controller, including the joystick, is housed in a pressure die cast aluminum enclosure.

Substantial equivalence

The Permobil powered wheelchair 1280 is substantial equivalent with respect to, intended use, energy source and materials, because those are identical to the predicate device(s).
The key changes are frame suspension and use of the Pilot + controller from Penny & Giles instead of the PG8 controller from Penny & Giles.

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Safety and effectiveness

The Permobil powered wheelchair 1280 has in substantials the same technological characteristics and the same safety and effectiveness as the predicate device(s) and the minor design changes declared in this submission do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1999

Mr. Bengt Persson
Quality Manager
Permobil A.B.
Engelbrekts Vag 101
S-191 62 Sollentuna,
Sweden

Re: K991658
Trade Name: Permobil Powered Wheelchair 1280
Regulatory Class: II
Product Code: ITI
Dated: July 7, 1999
Received: July 12, 1999

Dear Mr. Persson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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PERMOBIL POWERED WHEELCHAIR 1280

Indication for Use

The intended use is to provide indoor and outdoor mobility to persons restricted to a sitting position.

510(k) number

Not assigned at the writing of this submission

Device name

Not decided at writing of this submission
Working name, also use in this submission, 1280

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR 801.109) ☐ **or** **Over the counter use** ☒

Mark N Melkerson

for (Division Sign-Off)
Division of Ggeneral Restorative Devices

510(k) number K991657

Postadress: Box 120, S-861 23 Timrå, Sweden. *Besöksadress:* Årvältsvägen 10. *Telefon* +46-(0)60-59 59 00. *Telefax* +46-(0)60-57 52 50