



K993406

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

PERMOBIL POWERED WHEELCHAIR TRAX

Submitter Permobil AB
Box 120
S-861 23 Timrå
Sweden

DEC 18 2000

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 September 30 1999

Device name TRAX

Classification name
Powered wheelchair

Identification of predicate devices
Max90 (K870224)
Exterior (K870225)

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

Description of the device
The Permobil powered wheelchair TRAX is rear wheel driven, battery powered, motor driven and is controlled by the Permobil wheelchair controller SAFEGATE. The user interface is a joystick manufactured by Sakai for proportional control of the speed and the steering.
The wheelchair is powered by two 12V 97 Ah gel batteries.
Theoretical driving range on the fully charged batteries is 30 - 50 km depending of the terrain the chair is driven on.
The wheelchair consists of the following basic sub-sections:

- Base with two direct-drive units with integrated parking brakes, two 10"x3" rear wheels, suspension with stabilizer and two 12V 97Ah batteries.
- Extendable and pivoted front, length adjustable 0-200 mm (0-8"), teleflex wire steering, suspension and two 8"x2,5" front wheels.
- SAFEGATE TRAX Power electronics.
- Seating system.

The base is of welded steel construction with laser cut sheet details.
The direct-drive units consist of two 12V DC permanent magnet motors with gears and integrated parking brakes.



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PERMOBIL POWERED WHEELCHAIR TRAX

Substantial equivalence

The Permobil powered wheelchair TRAX is substantial equivalent with respect to, intended use, energy source and materials, because those are identical to the predicate device(s).

Safety and effectiveness

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

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

TRAX

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR 801.109)

or

Over the counter use

(Division Sign-Off)
Division of General Restorative Devices

510(k) number _____



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bengt Persson
Quality Manager
Permobil AB
Engelbrekts vag 101
S-191 62 Sollentuna
Sweden

Re: K993406
Trade Name: Trax, Powered Wheelchair, Model 308686-00-0
Regulatory Class: II
Product Code: ITI
Dated: November 22, 2000
Received: November 22, 2000

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.

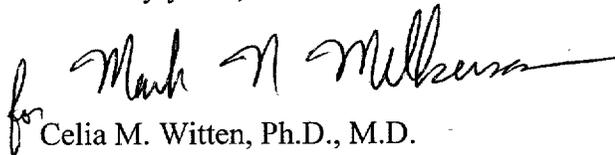
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Bengt Persson

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) 594-4659. 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,

A handwritten signature in black ink, appearing to read "for Mark N. Millerson". The signature is written in a cursive style and is positioned above the typed name.

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

Enclosure

510(k) notification K993406
FDA's request for additional information dated, January 6, 2000.

Enclosure D

510(k) Number (if known): K9930406
Device Name: Permobil TRAX
Indication For Use: Powered wheelchair, battery-operated device with wheels that is intended for medical purposes to provide indoor and outdoor mobility to persons restricted to a sitting position. Class II. The indoor use is depending of available space.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

for Mark A. Melkus
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993406