JUL 3 0 2002

K021264

Motion Concepts

510(k) Summary

Submitter: Motion Concepts

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Contact: David Ciolfe

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Date Prepared: April 16, 2002

Device Trade Name:
TRx-CG Power Positioning System with Center-of-Gravity Shifting Power Tilt, Recline, and Power Elevating Seat

Common Name:
Power Positioning System

Classification Name:
Powered Wheelchair

Identification of Predicate Device:
Permobil Powered Wheelchair 1280 (K991658)

Description of Device:

The TRX-CG Power Positioning System consists of a power tilt unit with optional power recline module, shear reduction module and power elevating seat module. The TRX-CG tilt system utilizes a center-of-gravity shift linkage, which causes the seat frame to shift progressively forward throughout the range of tilt. This enhances stability since the center of gravity is kept substantially in place while the user is tilting. The tilt system may be one of two similarly designed systems, one adapted for front wheel drive chairs and one adapted for rear wheel drive chairs. The tilt range of the power positioning system is 55°.

The recline function causes the position of the occupant's back to change by changing the position of the backrest with respect to the seat pan. The shear reduction module works in conjunction with recline to reduce the shear movement between the user and the backrest. This is accomplished using a linkage that slides the backrest down on the back posts as the back reclines. The range of recline of the TRX-CG is 168°.

The elevating seat module allows the user to elevate the entire system by up to 7 in. It consists of a 24 V ball drive pedestal actuator with a maximum capacity of 500 lbs and a maximum stroke of 7 in.

The maximum occupant weight for the TRX-CG system is up to 400 lbs depending on the features of the base and system modules selected. The minimum seat-to-floor height is 18 ½ in. The TRX-CG is assembled using laser-cut steel parts, steel tube, machined aluminum, delrin blocks and mounting hardware.

The power positioning modules may be activated via two options: using TRx switches or through the wheelchair manufacturer's controller. TRx switches consist of either push button switches or toggle switches.

Additional safety features include a drive lock-out which prevents the user from driving the power chair while tilted beyond a pre-set limit of 20° from the vertical or elevated beyond ½ in. Tilt limit is also available. Electrical components are a maximum of 24 volts with a fuse between the batteries and the relay box and current limiter built into the relay box. Stability of the TRX-CG was tested in our facility to ensure that the safety of the power wheelchair was not compromised by the addition of the power positioning system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2002

Motion Concepts
David Ciolfe
Operations Manager
84 Citation Drive
Concord, Ontario
Canada L4K 3C1

Re: K021264
Trade Name: TRZ-CG Power Positioning System with Center-of-Gravity Shifting Power Tilt, Recline, and Power Elevating Seat
Regulation Number: 890.3850
Regulation Name: Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: June 17, 2002
Received: June 18, 2002

Dear Mr. Coilfe:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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) Number (if known):_____

Device Name: TRx-CG Power Positioning System

Statement of Indications For Use:
The TRx-CG is appropriate for use by any individual who drives a power wheelchair and who desires or requires a change of position without having to utilize the services of an attendant. Needs for position changes include:

- **All positioning benefits associated with the tilt/recline product** —
  - **Comfort** - As with any individual – able-bodied or disabled – changes in position are necessary to maintain a state of comfort.
  - **Repositioning** - Individuals without adequate upper-body stability can be tilted to allow gravity to hold them in position.
  - **Pressure relief** - Individuals who wish, from time to time, to redistribute pressures from one area of the body to another, can do so by tilting and/or reclining. By changing the individual's orientation in space, pressures caused by gravity will shift.
- **Positioning/Versatility** — Individuals are able to reach higher elevations in a seated position, increasing their range of motion and accessibility.

Motion Concepts makes no claims as to the therapeutic effectiveness of the products. Our only claims relate to the ability of the products to provide safe and reliable powered repositioning on the equipment onto which they are installed. TRx-CG Power Positioning Systems are to be installed ONLY by qualified Dealers.

The above indications for use are identical to those of the Permobil Tilt/Recline/Elevating Seat System to which we are claiming substantial equivalence.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021264 MNM
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