K023426

NOV 21 2002

Motion Concepts

510(k) Summary

Submitter: Motion Concepts

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Contact: David Ciolfe

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Date Prepared: October 1, 2002

Device Trade Name:
TRX Vertical Positioner

Common Name:
Power Positioning System

Classification Name:
Powered Wheelchair

Identification of Predicate Device:
Levo Mobile LCM (K963817)

Description of Device:

The TRX Vertical Positioner is used to add the vertical positioning function to the tilt, recline, and elevating functions already available in with the TRX Power Positioning System defined in **K021264**. The Vertical Positioner functions by coordinating the elevating and reclining motion with an anterior tilt motion to change the user from an upright seated position to a vertical position and back again.

The TRX Vertical Positioner is assembled using primarily steel and aluminum, powder coated parts.

The vertical positioning is be activated using TRx switches consisting of either push buttons or toggle switches, or through the wheelchair joystick.

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". The system also includes extensions for the existing front anti-tipper wheels to provide additional front stability, and a lockout for the active track suspension in the vertical positioning mode. 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 Vertical Positioner was tested in our facility to ensure that the safety of the power wheelchair was not compromised by the addition of the system.

Statement of Indications for Use:

The TRX Vertical Positioner 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, reclining or vertical positioning. By changing the individual's orientation in space, pressures caused by gravity will shift.

- **Positioning/Versatility** — Individuals are able to reach higher elevations, increasing their range of motion and accessibility.

The TRX Vertical Positioner is used to add the vertical positioning function to the tilt, recline, and elevating functions already available in with the TRX Power Positioning System defined in **K021264**.

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 Vertical Positioners are to be installed ONLY by qualified Dealers.

Substantial Equivalence Comparison:

1100315 Ontario Limited claims that our product is substantially equivalent to the Mobile LCM as manufactured by Levo. The pre-existing device is classified as Class I as listed in 21 CFR Parts 890.3860. The Levo 510(k) document control number is K963817.

Both the TRx Vertical Positioner and the Levo Mobile LCM systems are devices that are used on power wheelchairs in order to provide the user with the capability to change his/her position from a seated position to a vertical position and back. Both products use similar components. Both are fabricated from steel and aluminum and have a generally similar mechanical operation. Both systems combine the anterior tilting and reclining action to achieve a vertical position.

The following is a comparison of the Mobile LCM and the TRx Vertical Positioner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

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

Re: K023426
Trade/Device Name: TRX Vertical Positioner
Regulation Number: 890.3860
Regulation Name: Powered Wheelchair (accessory)
Regulatory Class: Class II
Product Code: ITI
Dated: November 4, 2002
Received: November 8, 2002

Dear Mr. Ciolfe:

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 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,

Miriam C. Provost

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

Enclosure

510(k) Number (if known): K023426

Device Name: TRx Vertical Positioner

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The above indications for use are identical to those of the Levo Mobile LCM defined in **K963817** 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)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023426