

510(k) SUMMARY

Merits Health Products Co., LTD.
510(k) Premarket Notification

MAY - 8 2012

Submitter:

Merits Health Products Co., LTD.
No.18, Jingke Rd., Nantun Dist.
Taichung City 40852, Taiwan (R.O.C.)

Contact Person:

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Date Prepared:

November 30, 2011

Proprietary Name:

Merits Model R Series Positioning System for Powered Wheelchair

Common name:

Power Positioning System

Classification name:

Powered Wheelchair

Comparison to Predicate Devices:

The Merits R Series Positioning System is substantially equivalent to the Motion Concepts TRx-CG power Positioning System (#K021264). R Series Positioning System has the same intended uses and similar indications, technological characteristics and principles of operation.

Device Description

The R Series Positioning System for Powered Wheelchair is designed for use with power wheelchairs. The R Series Positioning System for Powered Wheelchair use the Merits Model P323 Power Wheelchair as the base unit for the tilting and reclining System. The Positioning System and base unit is to be sold together. Model P323 Powered Wheelchair is battery powered, center wheel motor driven and is controlled by the PG power wheelchair VR-2 60amp controller. The user interface is a joystick. P323 is powered by two 12 VDC 64ah batteries. The batteries are charged by 5A off-board charger connect with 3-pin Microphone Connector to charging socket on joystick. The approximate driving range on fully charged batteries is up to 38km (24mi). The chair frame is a rivet nut and welded steel construction and includes two center drive wheels with drive units (including motor, gear, brake), batteries and front and rear 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 wheelchair 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.

The intended function of the R Series Positioning System for Powered Wheelchair is to aid in the pressure relief of persons confined to a wheelchair, by providing a method of tilting the seat and reclining the seat back.

The R series Positioning System consists of tilt, recline and shear reduction power seat modules. The tilting and reclining systems are separate modules and are independent of each other. As such, they will be offered as either a complete tilt/recline system, or as a separate tilt system or reclining system depending upon the user's needs.

The tilting and reclining systems are actuated by 24V DC motorized linear actuator. The tilt system include one motorized linear actuator (Manufacturer: Moteck / Model: FD-24-A4-323) causes the seat frame to shift forward. This enhances stability since the center of gravity is kept substantially in place while the user is tilting.

The recline system include one motorized linear actuator (Manufacturer: Moteck / Model: FD-24-A4-278) change the position of the backrest with respect to the seat pan. The shear reduction module works with recline function to reduce the shear movement between the user and the backrest. The reclining system also includes a movable leg rest feature.

There two basic models included in the R Series Positioning System. They are Model R153(tilt) and R154(tilt +reclining).

The upholstery of the device complies with EN 1021-1/-2:2006: Furniture: Assessment of the ignitability of upholstered furniture: Ignition source: Smouldering cigarette/ Match flame equivalent.

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The Merits R Series Positioning System is substantially equivalent to the Motion Concepts TRx-CG power Positioning System (#K021264). Both products are battery power, motorized, seating systems designed for use with powered wheelchairs. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to aid in the pressure relief of persons confined to a powered wheelchair, by providing a method of tilting the seat and reclining the seat back. Additional, they are all constructed from the same basic materials, have the same basic operational principles and all use DC batteries as their source of power.

Although there are some minor differences between R Series Positioning System and its predicate device, they raise no new issues of safety or effectiveness. Performance data demonstrate that the R Series Positioning System is safe. The non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Intended Use

The Merits Model R series Positioning System for Powered Wheelchair is intended for people using a powered wheelchair and requiring positional change.

Its intended function and use is to aid in the pressure relief to persons confined to a powered wheelchair, by way of tilt and reclining seat back.

Discussion of Non-clinical Tests Performed for Determinations of Substantial equivalence are as follows:

- ISO 7176-1:1999 Determination of Static Stability
- ISO 7176-2:2001 Determination of Dynamic Stability of electric wheelchairs
- ISO 7176-3:2003 Determination of effectiveness of brakes
- ISO 7176-4:2008 Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5:2008 Determination of overall dimensions, mass and maneuvering space
- ISO 7176-6:2001 Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-8:2009 Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-9:2009 Climatic tests for wheelchairs
- ISO 7176-10:2008 Determination of obstacle-climbing ability of electrically power wheelchairs
- ISO 7176-11:1992 Test dummies
- ISO 7176-13:1989 Determination of coefficient of friction of test surfaces
- ISO 7176-14:2008 Power and Control Systems for Electric Powered Wheelchairs and Scooters-Requirements and Test methods.
- ISO 7176-15:1996 Requirements for Information Disclosure, Documentation and Labeling
- ISO 7176-21:2009 Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters and Battery Chargers.
- IEC 60601-1:1988 Medical electrical equipment Part 1: General requirements for safety
- IEC 60601-1-2:2007 Electromagnetic Compatibility - Requirements and Tests
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices
- EN 1021-1:2006 Furniture Assessment of the ignitability of upholstered furniture : Ignition source: Smouldering cigarette
- EN 1021-2:2006 Furniture Assessment of the ignitability of upholstered furniture : Ignition source: Match flame equivalent

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

Conclusions

According to comparison table, the differences on weight capacity, function of elevate, recline and dimension of width do not deleteriously affect the safety and effectiveness of the device.

So based on the design, performance specifications and testing and intended use, the Merits R Series Positioning System for Powered Wheelchair is substantially equivalent to the currently marketed device Motion Concepts TRx-CG power Positioning System (#K021264).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room—WO66-G609
Silver Spring, MD 20993-0002

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MAY - 8 2012

Re: K113577

Trade/Device Name: Merits Health Products R Series Positioning System for Powered
Wheelchair

Regulation Number: 21 CFR 890.3860

Regulation Name: Powered wheelchair

Regulatory Class: Class II

Product Code: ITI

Dated: March 29, 2012

Received: March 29, 2012

Dear Mr. Chao:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

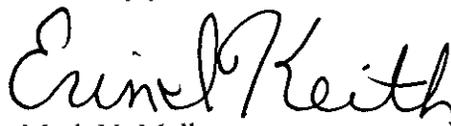
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number:

Device Name: Merits Health Products R Series Positioning System for Powered Wheelchair

Indications For Use: The Merits Model R series Positioning System for Powered Wheelchair is intended for people using a powered wheelchair and requiring positional change. Its intended function and use is to aid in the pressure relief to persons confined to a powered wheelchair, by way of tilt and reclining seat back.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113577