



Food and Drug Administration
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June 30, 2015

Motion Concepts
Dona Bhamra
Senior Quality and Regulatory Affairs Manager
84 Citation Dr. Unit #1
Concord, ON L4K 3C1
Canada

Re: K150574
Trade/Device Name: Modular Power Positioning System
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 19, 2015
Received: May 20, 2015

Dear Dona Bhamra:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150574

Device Name

Modular Power Positioning System

Indications for Use (Describe)

The Modular Power Positioning system 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.

Positioning: Individuals without adequate upper-body stability can be tilted to allow gravity to hold them in position.

Pressure Relief or Reduction: Individuals who wish, from time to time, to redistribute pressure 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

I. SUBMITTER

Motion Concepts
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Phone: 905-695-0134
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Contact person: Dona Bhamra
Date Summary Prepared: 06-May-2015

II. DEVICE

Device Proprietary Name: Modular Power Positioning System
Common Name: Powered Wheelchair
Classification Regulation: 21 CFR, 890.3860
Product Code: ITI
Classification of Device: Class II

III. PREDICATE DEVICE

The predicate device is TRZ CG Power Positioning System, which was cleared under K021264.

IV. DEVICE DESCRIPTION

The Modular Power Positioning System is a seating system which is added to a power wheelchair base to provide three basic functions, power tilt, power recline including shear reduction, and power elevate (or lift). Note the Modular power positioning system in itself does not include any wheelchair base components such as wheelchair frame, drive train, drive controls, wheels, brakes, batteries, suspension etc.

The Tilt unit utilizes a center of gravity shift linkage, which causes the seat frame to shift progressively forward throughout the range of tilt. This enhances the stability since the center of gravity is kept substantially in place while the user is tilting. The Tilt unit may be one of two similarly designed systems, one designed for 50° tilt, and one for 45° tilt which is integrated with the 12 inch linkage style lift.

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 works in conjunction with Recline to reduce the shear movement between the user and the backrest. The latter is accomplished by using a linkage that slides the backrest down on the back posts as the back reclines. The range of Recline is 90° to 168°.

The Elevating seat (or Lift) module allows the user to elevate the entire seat by up to 12 inches. It consists of a standard linkage style mechanism.

The maximum occupant weight for the system is up to 300 lb depending on the features of the wheelchair base and system modules selected. The Modular Power Positioning System is assembled using primarily laser-cut steel parts, steel tube, machined aluminum, and mounting hardware.

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

Safety features include a drive lock-out which prevents the user from driving the power chair while tilted, reclined, or elevated beyond a certain pre-set limit. Electrical components are maximum 24 volts, and include a current limiter in the relay box. Stability of the Modular Power Positioning System was tested on various wheelchairs commonly used for power positioning applications. These tests were conducted to ensure the safety of the power wheelchair was not compromised by the addition of the power positioning system.

V. INDICATIONS FOR USE

The Modular Power Positioning system 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.

Positioning — Individuals without adequate upper-body stability can be tilted to allow gravity to hold them in position.

Pressure Relief or Reduction — Individuals who wish, from time to time, to redistribute pressure 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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Modular Power Positioning System is substantially equivalent to the TRZ-CG with power elevating seat, tilt and recline.

Both the Modular Power Positioning System and the TRZ-CG are seating systems which are added to power wheelchairs to provide three basic functions, Power Tilt, Power Recline including Shear Reduction, and a Power Elevating Seat, with target populations of people with limited mobility such as quadriplegics. Both systems are generally fabricated from the same materials with similar mechanical operation. Both have similar safety features and meet the same standards.

The most significant difference between the Modular Power Positioning System the predicate device is that the predicate device uses a 7” tower style actuator for lift, whereas the proposed device uses a 12” linkage style mechanism. This increase in lift will have an impact on the stability of the wheelchair, however testing has shown that the resulting stability is still within the accepted range. In addition, the Modular Power Positioning System provides a maximum tilt angle of 50 degrees, whereas the predicate device provides 55 degrees. 50 degrees is an industry standard, and adequate for the intended use of the Modular Power Positioning System. This difference in maximum tilt angle does not adversely affect the safety or effectiveness of the system.

In addition to the drive lock out (DLO) system of the original system which is used to disable the wheelchair drive system when the seating system reaches a factory pre-set position, the new system also includes a second trigger which enables the reduced drive (RD) feature standard on most wheelchairs. This system allows the user to drive at a maximum of 25 to 30% speed when the seating system reaches a second, lower factory pre-set position. The system stability was tested for both driving modes, Full Drive (FD) and Reduced Drive (RD). For testing details see Bench Testing, Section 18 below.

Due to the improved mechanical efficiency of the Tilt, Recline, and Lift linkages, the new system uses less electrical power (24 VDC / 4 Amps) than the predicate device (24 VDC / 8 Amps) and does adversely affect the safety or effectiveness of the device.

The Modular Power Positioning System includes a seat depth range of 15-22 compared to predicate which offers 16-24 inches, and a back height range of 18-30 inches compared to predicate which offers 18-26 inches. These new ranges are more effective in meeting user needs, and stability testing has shown the safety would not be adversely affected.

VII. PERFORMANCE DATA

The following performance data has been provided in support of the substantial equivalence determination.

- **Biocompatibility Testing**

Bio-Compatibility was evaluated for all surface materials where prolonged skin contact may occur. Cytotoxicity testing per ISO 10993 Part 5: Testing for in vitro cytotoxicity was performed on all skin contacting surface materials such as Meshtex, Startex, Spacetex 4000U™, O-Vinyl, Style 6499 Polyester and Integral Skin foam.

- **Electrical Safety and electromagnetic compatibility (EMC)**

Electromagnetic Compatibility has been conducted on the Modular power positioning system. The system complies with RESNA Section 21, Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters.

- **Software Verification and Validation Testing**

Software verification and validation testing have been conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered to have a "Moderate level of Concern" because "prior to mitigation of hazards, a failure of the Software Device could result in Minor Injury, either to a patient or to a user of the device."

- **Mechanical and acoustic testing**

Mechanical testing of the Modular Power Positioning System was carried out to cover functional verification and device performance. Testing established correct

functionality according to the relevant ANSI/RESNA standards. No acoustic testing was required to demonstrate device safety and effectiveness of the subject device.

- **Animal Study**

Animal performance testing was not required to demonstrate the safety and effectiveness of the subject device.

- **Clinical Studies**

Clinical testing was not required to demonstrate the safety and effectiveness of the subject device.

Predicate Device Comparison Table

	Modular Power Positioning System (Subject Device)	TRZ CG (Predicate Device)
Indications for Use	<p>- All positioning benefits associated with the tilt/recline product — comfort, repositioning, pressure relief</p> <p>- Positioning/Versatility — Individuals are able to reach higher levels, increasing their range of motion and accessibility</p>	Same
Target Population	<p>- Quadriplegics</p> <p>- persons with ALS, MS, spinal muscular atrophy, and any other disability which causes the individual to require a power wheelchair and not be able to reach an elevated position or shift his/her weight</p>	Same
Design	<p>-mechanism includes a seat which tilts, reclines, and elevates</p> <p>- tilt, recline, and elevating seat utilize linear actuators</p>	Same except elevating function utilizes tower style actuator.
seat width range	16 to 24 inches	16 to 24 inches
seat depth range	15 to 22 inches	16 to 24 inches
back height	18 to 30 inches	18 to 26 inches

	Modular Power Positioning System (Subject Device)	TRZ CG (Predicate Device)
range		
Materials	- steel tube and plate, aluminum, powder-coated	Same
Motor type	Linear actuator, gear reduction screw type	Linear actuator, gear reduction screw type
Energy Used	24 VDC Wheelchair Batteries 4 Amps	Same 8 Amps
Performance - Tilt	50°	55°
Performance - Recline	168°	168°
Lift (Elevating Seat)	12 inches	7 inches
Mechanical Safety	- wheelchair remains stable with fully elevated, tilted, and reclined seat — center-of-gravity shift further enhances stability - drive lock-out prevents user from driving power chair while tilted beyond a pre-set limit - tilt limit is available	Same
Where Used	- private residences - chronic-care facilities - indoors, outdoors	Same
Electrical Safety	- electrical components are 24 volts maximum - current limit built into relay box	Same
Stability Safety	- includes DLO (drive lock out) trigger - includes RD (reduced drive) trigger	Includes DLO only
Standards Met	- RESNA, see details below	Same

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-2:2009 Section 2: Determination of Dynamic Stability
- ANSI/RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ANSI/RESNA WC-2:2009 Section 9: Climatic Tests
- ANSI/RESNA WC-1:2009 Section 11: Test Dummies
- ANSI/RESNA WC-1:2009 Section 13: Determination of Coefficient Friction of Test Surfaces
- ANSI/RESNA WC-1:2009 Section 14: Power and Control Systems Requirements and Test Methods
- ANSI/RESNA WC-1:2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- ANSI/RESNA WC-1:2009 Section 16 Resistance to Ignition of Upholstered Parts, or EN12184:2014 section 8.10 Resistance to Ignition
- ANSI/RESNA WC-2:2009 Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters
- ISO 10993:2009 Biological Evaluation of Medical Devices
- EN 1021-1/-2:2006: Testing of Ignitability For Upholstered Furniture
California Technical Bulletin 117-2013: Requirements For Testing The Smolder Resistance Of Materials Used In Upholstered Furniture

Conclusions

The Modular Power Positioning System has the same intended use and similar technological characteristics as the TRZ CG Power Positioning Device, K021264. The non-clinical testing and the predicate device comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety and effectiveness. Thus the Modular Power Positioning System is substantially equivalent to the predicate device, has passed all the necessary testing and is considered to be safe for user operation.