



March 8, 2019

Motion Concepts

Dona Bhamra

Senior Quality and Regulatory Affairs Manager

84 Citation Drive, Unit #1

Concord, L4K 3C1 Ca

Re: K182995

Trade/Device Name: Bariatric Power Positioning System (BPPS)

Regulation Number: 21 CFR 890.3860

Regulation Name: Powered Wheelchair

Regulatory Class: Class II

Product Code: ITI

Dated: November 29, 2018

Received: December 6, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for 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)

K182995

Device Name

Bariatric Power Positioning System (BPPS)

Indications for Use (Describe)

The Bariatric 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.

- 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.

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 Bariatric Power Positioning System	

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

I. SUBMITTER

FDA Establishment Registration Number: 9615350

Address: Motion Concepts
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Phone: 905-695-0134

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Contact person: Dona Bhamra

Date Summary Prepared: 24-Oct-2018

II. DEVICE

Device Proprietary Name: Bariatric Power Positioning System (BPPS)

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 the Motion Concepts Modular Power Positioning System (MPPS) cleared under K150574.

IV. DEVICE DESCRIPTION

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

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The power Tilt function causes the position of the occupant to change by tilting the whole seat, including the seat pan, backrest, foot supports, and arm supports. The range of tilt is 0° to 50°.

The power 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 recline function is also useful for the redistribution of pressure and providing improved body position for certain user activities. The range of Recline is 90° to 150°.

The maximum occupant weight for the Bariatric Power Positioning System is up to 400 lb depending on the wheelchair powerbase and seating features selected. The BPPS is assembled using primarily laser-cut steel parts, steel tube, machined aluminum, and mounting hardware.

The power positioning modules may be activated via two options: using separate switches or through the wheelchair base manufacturer's joystick control.

Safety features include a drive lock-out which prevents the user from driving the power chair while tilted or reclined beyond a certain pre-set limit. Electrical components are maximum 24 volts and include a current limiter in the relay box. Stability of the Bariatric Power Positioning System was tested on wheelchair powerbases 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 Bariatric Power Positioning System.

V. INDICATIONS FOR USE

The Bariatric 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.

o **Benefits associated with the tilt/recline product:**

- o **Comfort** — as with any individual — able-bodied or disabled — changes in position are necessary to maintain a state of comfort.

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

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

Both the Bariatric Power Positioning System (BPPS) and the predicate device Modular Power Positioning System (MPPS) are seating systems which are interfaced with wheelchair power bases to provide two basic functions, Power Tilt, and Power Recline including Shear Reduction. Both systems are generally fabricated from the same materials with similar mechanical operation. Both have similar safety features and meet the same standards.

In addition, the BPPS has the same drive lock out (DLO) and reduce drive speed (RDS) limits as the MPPS. The drive lock out (DLO) limit is used to disable the wheelchair drive system when the seating system reaches a factory pre-set position. The reduced drive speed (RDS) feature comes standard on most wheelchair powerbases, and restricts the wheelchair drive system to a maximum of 25% to 30% speed when the seating system reaches a second, lower factory pre-set position (prior to Drive Lock Out). The system stability was tested in all three modes, Full Drive Speed (FDS), Reduced Drive Speed (RDS) and Drive Lock Out (DLO). (For testing details see Performance Testing - Bench)

It is noted that the BPPS provides a maximum recline angle of 150 degrees, whereas the predicate device MPPS provides up to 168 degrees. Even though, the BPPS achieves a slightly lower maximum recline angle, it still maintains the same technological characteristics and has the same intended use as the predicated device.

The MPPS (predicate) offers a lift (elevate) mechanism as an optional seat function. This option will not be made available on the BPPS, however the absence of the lift will not reduce the effectiveness of the MPPS tilt and recline functions. It is for this reason that the Intended Use of the BPPS does not include "Positioning/Versatility

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– individuals are able to reach higher elevations in a seated position, increasing their range of motion and accessibility”. This difference will not adversely affect the safety or effectiveness of the BPPS.

The most significant difference between the BPPS and the predicate device MPPS is the maximum user weight. The BPPS is rated for maximum 400 lb users and the MPPS is rated for maximum 300 lb users. It is noted that the BPPS and MPPS are only made available for powerbases with appropriate respective load ratings. The increase in weight capacity on the BPPS will have an impact on the stability of the wheelchair, however test results indicate that the systems stability, on the applicable powerbases, is still within the accepted range.

VII. PERFORMANCE DATA

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

- **Biocompatibility Testing**
 - o Bio-Compatibility testing requirements were evaluated for all potential body (skin) contacting materials. Cytotoxicity testing was performed per ‘ISO 10993 Part 5: Testing for in vitro cytotoxicity’, and Dermal Sensitization testing and/or Primary Skin Irritation testing was performed per ‘ISO 10993 Par10: Tests for irritation and skin sensitization’. Testing was conducted on all body contact materials on the BPPS, including: Meshtex fabric, Startex fabric, Spacetex 4000U™ fabric, O-Vinyl fabric, Style 6499 Polyester fabric, Rotex FR Polyester fabric, Self-Skinning Skin PU Foam (Bolasto F380 (RN7548).
- **Software Verification and Validation Testing**
 - o 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.”
- **Electrical Safety and electromagnetic compatibility (EMC)**
 - o Electromagnetic Compatibility testing has been conducted on the Bariatric Power Positioning System. The system complies with RESNA Section 21, Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters.
- **Mechanical and acoustic testing**

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- o Mechanical testing of the Bariatric 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**
 - o Animal performance testing was not required to demonstrate the safety and effectiveness of the subject device.
- **Clinical Studies**
 - o Clinical testing was not required to demonstrate the safety and effectiveness of the subject device.

The following table summarises the comparison of technological characteristics with predicate the device:

	Bariatric Power Positioning System (Subject Device)	Modular Power Positioning System (Predicate Device)
Indications for Use	The Bariatric 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. - Benefits associated with the tilt/recline product: - o Comfort — as with any individual – able-bodied or disabled – changes in position are necessary to maintain a state of comfort. - o Positioning — Individuals without adequate upper-body stability can be tilted to allow gravity to hold them in position. - o 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. Motion Concepts makes no claims as to the therapeutic effectiveness of the products. Our only claims relate to the	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.

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	Bariatric Power Positioning System (Subject Device)	Modular Power Positioning System (Predicate Device)
	ability of the products to provide safe and reliable powered repositioning on the equipment onto which they are installed.	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.
Target Population	- Quadriplegics - persons with ALS, MS, spinal muscular atrophy, and any other disability which causes the individual to require a power wheelchair and not be able shift his/her weight	Same
Design	- mechanism includes a seat which tilts, and reclines - tilt, and recline seat utilize linear actuators	Same
Materials	- steel tube and plate, aluminum, powder-coated	Same
Performance – Tilt	50°	50°
Performance – Recline	150°	168°

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	Bariatric Power Positioning System (Subject Device)	Modular Power Positioning System (Predicate Device)
Seat Width range	20 to 26 inches	16 to 24 inches
Seat depth range	16 to 23 inches	15 to 22 inches
Lift (Elevating Seat)	N/A	12 inches
Back height range	18 to 30 inches	18 to 30 inches
Mechanical Safety	- wheelchair remains stable with fully 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
Energy Used	- 24 VDC Wheelchair Batteries	Same
Motor Type	Linear actuator, Gear reduction screw type	Same
Motor Voltage	24VDC	Same
Motor Maximum Current	4 Amps	Same
Power	96W	Same
Stability Safety	- includes DLO (drive lock out) trigger - includes RD (reduced drive) trigger	Same
Standards Met	- RESNA, see details below	Same

Standards Met

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-2:2009 Section 2: Determination of Dynamic Stability Of Electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths

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- ANSI/RESNA WC-2:2009 Section 9: Climatic Tests for Electrically Powered Wheelchairs
- 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-2:2009 Section 14: Power and Control Systems for Electrically Powered Wheelchairs – 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 EN 12184:2014 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 Part 5: Biological Evaluation of Medical Devices – Tests For In Vitro Cytotoxicity
- ISO 10993:2010 Part 10: Biological Evaluation of Medical Devices – Tests for irritation and skin sensitization
- EN 1021-1/-2:2014: Testing of Ignitability For Upholstered Furniture
- California Technical Bulletin 117-2013: Requirements, Test Procedure and Apparatus For Testing The Smolder Resistance Of Materials Used In Upholstered Furniture

Conclusion

The Bariatric Power Positioning System has the similar intended use and same technological characteristics as the predicate Modular Power Positioning Device, K150574. 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 Bariatric 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.