August 13, 2019

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

Re: K191376
Trade/Device Name: Modular Power Standing System
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: May 17, 2019
Received: May 23, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Vivek J. Pinto, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191376

Device Name
Modular Power Standing System (MPSS)

Indications for Use *(Describe)*
The Modular Power Standing System is appropriate for use by individuals who drive a power wheelchair and cannot stand up on their own. The Modular Power Standing System allows such users to change position including from seating to standing, standing to seating, or any position in between. The device is appropriate for indoor and outdoor use. 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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<br>84 Citation Drive, Unit 1<br>Concord, Ontario, L4K 3C1 |
| Phone: | 905-695-0134 |
| Fax: | 905-695-0138 |
| Contact person: | Dona Bhamra |
| Date Summary Prepared: | 1-Aug-2019 |

## II. DEVICE

| | |
|---|---|
| Device Proprietary Name: | Modular Power Standing System (MPSS) |
| Common Name: | Standup Wheelchair |
| Classification Regulation: | 21 CFR, 890.3900 |
| Product Code: | IPL |
| Classification of Device: | Class II |

## III. PREDICATE DEVICE

| | |
|---|---|
| Predicate Device: | Levo C3 Power Wheelchair<br>K083017<br>Product Code IPL<br>21 CFR 890.3900 |
| Reference Device: | Motion Concepts Modular Power Positioning System<br>K150574<br>Product Code ITI<br>21 CFR 890.3860 |

## IV. DEVICE DESCRIPTION

The Modular Power Standing System (MPSS) is a seating system which is added to a wheelchair powerbase to provide four basic functions: power stand-up, power tilt, power recline including shear reduction, and power elevate. It can be operated in private residences, chronic care facilities, indoor and outdoors. Note the MPSS in itself does not include any wheelchair base components such as wheelchair frame, drive train, drive controls, wheels, brakes, batteries, suspension etc.

The Stand function is used to orient the user in an upright position. The mechanism consists of linkages driven by linear actuators. The system includes both a knee support and a chest support to help stabilize the user in the standing position.

The Tilt function is used to change the seating inclination angle of user. The mechanisms consist of linkages driven by linear actuators. The range of tilt is 0° to 45°.

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 mechanisms consist of linkages driven by linear actuators. The range of Recline is 90° to 178°.

The Elevating seat module allows the user to elevate the entire seat. The mechanisms consist of linkages driven by linear actuators. The range of elevation is 6.5 inches.

The maximum occupant weight for the system is 250 lb. The Modular Power Standing 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 powerbase manufacturer supplied joystick.

Safety features include a drive lock-out and reduced drive mode which are activated when any of the power functions are activated beyond pre-set limits. The system also includes front castor locks to provide additional front stability when in stand mode. Electrical components are maximum 24 volts and include current limiting within the seat control box. Stability of the Modular Power Standing System was tested on the powerbase selected for this application. These tests were conducted to ensure the safety of the power wheelchair was not compromised by the addition of the Modular Power Standing System.

## V. INDICATIONS FOR USE

The Modular Power Standing System is appropriate for use by individuals who drive a power wheelchair and cannot stand up on their own. The Modular Power Standing System allows such users to change position including from seating to standing, standing to seating, or any position in between. The device is appropriate for indoor and outdoor use. 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 new Modular Power Standing System was designed to add the standing function option to the existing Motion Concepts Modular Power Positioning System functions of tilt, recline, and elevate. This new standing feature functions similarly to the Levo C3 K083017, which will therefore serve as the Predicate device. In order to further demonstrate safety and effectiveness the Modular Power Position System K150574 will also be used as a reference device.

**Predicate device: Levo C3 (K083017)**

Both the subject device Modular Power Standing System (MPSS) and the predicate device Levo C3 Power Wheelchair are systems which provide a stand-up feature, allowing users to reposition themselves from seating to standing and vice versa. Both systems include both a knee support and a chest support to help stabilize the user in the standing position.

The two systems are equivalent with respect to the following:

- indications for use
- target population

- safety features
- general design
- use of materials
- standards met

The seat size (width/depth/back height) differs in that the MPSS does not offer the smaller seat sizes offered on the predicate device. This difference does not affect the effectiveness of the MPSS over the range offered.

**Reference Device Motion Concepts Modular Power Position System (K150574)**

Both the subject device Modular Power Standing System (MPSS) and reference device Modular Power Positioning System are seating systems that provide three basic functions: power tilt, power recline including shear reduction and power elevate.

The two systems are equivalent with respect to the following:

- safety features
- electrical safety
- general design
- use of materials
- energy used
- motor type used
- standards met

The seat size (width/depth/back height) differs in that the MPSS does not offer the larger seat sizes offered on the referenced device. This difference does not affect the effectiveness of the MPSS over the range offered.

The elevate range on the referenced device is less than that offered on the MPSS, however the effectiveness is maintained as the standing function improves the reach and accessibility available to the user.

## VII. PERFORMANCE DATA

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

- **Biocompatibility Testing**
  - 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 MPSS, including: Meshtex fabric, Startex fabric, Spacetex 4000U™ fabric, O-Vinyl fabric, Style 6499 Polyester fabric, Self-Skinning Skin PU Foam (Bolasto F380 (RN7548)).
- **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."
- **Electrical Safety and electromagnetic compatibility (EMC)**

  - Electromagnetic Compatibility testing has been conducted on the Modular Power Standing System. The system complies with ISO 7176-21, Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters.

- **Mechanical and acoustic testing**
  - Mechanical testing of the Modular Power Standing System was carried out to cover functional verification and device performance. Testing established correct functionality according to the relevant ISO 7176 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.

The following table provides a comparison of technological characteristics with the predicate device (Levo X3) and the reference device (Modular Power Positioning System) to demonstrate substantial equivalence.

| | **Subject Device** | **Predicate (A)** | **Reference device (B)** | **Comparison** |
|---|---|---|---|---|
| | **Motion Concepts Modular Power Standing System** | **Levo C3** | **Motion Concepts Modular Power Positioning System** | |
| 510k number | N/A | K083017 | K150574 | N/A |
| Product Code | IPL 890.3900 | IPL 890.3900 | ITI 890.3860 | The subject device is identical to (A) |
| Indications for Use | The Modular Power Standing System is appropriate for use by individuals who drive a power wheelchair and cannot stand up on their own. The Modular Power Standing System allows such users to change position including from seating to standing, standing to seating, or any position in between. The device is appropriate for indoor and outdoor use. 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. | The LEVO C3 power wheelchair with optional seating and standing position function may be of interest for any individuals who needs a power wheelchair and cannot stand up on their own such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.. | N/A | The subject device is equivalent to (A). |

| | Subject Device | Predicate (A) | Reference device (B) | Comparison |
|---|---|---|---|---|
| | **Motion Concepts Modular Power Standing System** | **Levo C3** | **Motion Concepts Modular Power Positioning System** | |
| Picture (in standing mode) |  |  | N/A | The subject device is equivalent to (A) for standing function. |
| Picture (in tilt/recline/elevate mode) |  |  |  | The subject device is equivalent to (B) for tilt, recline, and elevate functions. |
| Target Population | - Paraplegics or quadriplegics<br>- People with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, and other diseases and conditions which cause the individual to require a power wheelchair and not be able to shift his/her weight | The LEVO C3 power wheelchair with optional seating and standing position function may be of interest for any individuals who needs a power wheelchair and cannot stand up on their own such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.. | - Quadriplegics<br>- 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 | The subject device is equivalent to (A). |
| Design | Link based mechanisms powered by electro-mechanical linear actuators | Link based mechanisms powered by electro-mechanical linear actuators | Link based mechanisms powered by electro-mechanical linear actuators | The subject device is equivalent to (A) and (B). |
| Materials | steel tube and plate, aluminum, powder-coated | steel tube and plate, aluminum, powder-coated | steel tube and plate, aluminum, powder-coated | The subject device is equivalent to (A) and (B). |
| Weight Capacity | 250 lbs | 310 lbs | 300 lbs (250lbs with elevate) | The subject device is equivalent to (B) with elevate. |
| Performance – Tilt | 45° | 35° | 50° | The subject is functionally equivalent to (A) and (B) |
| Performance – Recline | 178° | *Info Not available* | 168° | The subject device is functionally equivalent to (A) and (B). It is noted that the slight |

| | Subject Device | Predicate (A) | Reference device (B) | Comparison |
|---|---|---|---|---|
| | **Motion Concepts Modular Power Standing System** | **Levo C3** | **Motion Concepts Modular Power Positioning System** | |
| | | | | increase in maximum amount of recline compared to (B) is required to provide an effective stand option |
| Performance – Elevate | 6.5” | N/A | 12” | The subject device has less elevate than (B), This is offset by the stand feature which offers alternatives for comfort, positioning and versatility. |
| Seat width range | 16 to 21 inches | 12.5 to 20.5 inches | 15 to 24 inches | The subject device has smaller width range than (A) or (B) |
| Seat depth range | 16 to 20 inches | 13.75 to 25 inches | 15 to 22 inches | The subject device has smaller depth range than (A) or (B) |
| Back height range | 20 to 28 inches | 12 to 21.5” | 18 to 30 inches | The subject device has smaller back height range than (B) |
| Mechanical Safety | - wheelchair remains stable when fully tilted, reclined seat, elevated, standing<br>- speed is reduced when patient is positioned beyond pre-set limits.<br>- drive lock-out prevents user from driving power chair while tilted beyond a pre-set limits<br>- tilt limit is available<br>- Front caster lock to reduce risk of tipping forward while in stand-up position | - The speed is reduced to half speed as soon as the patient is not in the sitting position | - wheelchair remains stable with fully elevated, tilted, and reclined seat – center-of-gravity shift further enhances stability<br>- drive lock-out prevents user from driving power chair while tilted beyond a pre-set limit<br>- speed is reduced when patient is positioned beyond pre-set limits.<br>- tilt limit is available | The subject device includes safety features equivalent to those listed for both (A) and (B) |
| Where Used | - private residences<br>- chronic-care facilities<br>- indoors, outdoors | The product provides high indoor and outdoor mobility on surfaces like tar, grass and gravel | - private residences<br>- chronic-care facilities<br>- indoors, outdoors | The subject device is equivalent to (A) and (B). |
| Electrical Safety | - electrical components are 24 volts maximum<br>- current limit built into relay box | *Info Not available* | - electrical components are 24 volts maximum<br>- current limit built into relay box | Identical to (B) |
| Energy Used | 24 VDC Wheelchair Batteries | 24 VDC Wheelchair Batteries | 24 VDC Wheelchair Batteries | Identical to (A) and (B). |

| | Subject Device | Predicate (A) | Reference device (B) | Comparison |
|---|---|---|---|---|
| | **Motion Concepts Modular Power Standing System** | **Levo C3** | **Motion Concepts Modular Power Positioning System** | |
| Power stand-up feature | Chest support and knee support standard | Chest support and knee support standard | Not Applicable | The subject device is equivalent to (A) |
| Motor Type | Linear actuator,<br>Gear reduction screw type | *Info Not available* | Linear actuator,<br>Gear reduction screw type | Identical to (B) |
| Motor Voltage | 24VDC | *Info Not available* | 24VDC | Identical to (B) |
| Motor Maximum Current | 4 Amps | *Info Not available* | 4 Amps | Identical to (B) |
| Power | 96W | *Info Not available* | 96W | Identical to (B) |
| Standards Met | ISO 7176 see details below | ISO 7176<br>ANSI/RESNA | RESNA WC-1:2009<br>RESNA WC-2:2009 | The subject device is equivalent to (A) and (B). |

Standards Met

| Standard | Description | FDA Recognition Number |
|---|---|---|
| ISO 7176-1:2014 | Wheelchairs – Part 1: Determination of static stability | 16-195 |
| ISO 7176-2:2017 | Wheelchairs – Part 2: Determination of dynamic stability of electrically powered wheelchairs | 16-202 |
| ISO 7176-3:2012 | Wheelchairs – Part 3: Determination of effectiveness of brakes | 16-192 |
| ISO 7176-4:2008 | Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range | 16-162 |
| ISO 7176-5:2008 | Wheelchairs – Part 5: Determination of dimensions, mass and maneuvering space | 16-163 |
| ISO 7176-6:2018 | Wheelchairs – Part 6: Determination of maximum speed of electrically powered wheelchairs | 16-204 |
| ISO 7176-7:1998 | Wheelchairs – Part 7: Measurements of seating and wheel dimensions | 16-196 |
| ISO 7176-8:2014 | Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths | 16-197 |
| ISO 7176-9:2009 | Wheelchairs – Part 9: Climatic tests for electric wheelchairs | 16-167 |
| ISO 7176-10:2008 | Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs | 16-164 |
| ISO 7176-11:2012 | Wheelchairs – Part 11: Test dummies | 16-190 |
| ISO 7176-13:1989 | Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces | 16-25 |
| ISO 7176-14:2008 | Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters – Requirements and test methods | 16-165 |

| Standard | Description | FDA Recognition Number |
|---|---|---|
| ISO 7176-15:1996 | Wheelchairs – Part 15: Requirements for information disclosure, documentation and labelling | 16-27 |
| ISO 7176-16:2012 | Wheelchairs – Part 16: Resistance to ignition of postural support devices | 16-191 |
| ISO 7176-21:2009 | Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers | 16-166 |
| ISO 7176-22:2014 | Wheelchairs – Part 22: Set-up procedures | 16-198 |
| ISO 7176-30:2018 | Wheelchairs – Part 30: Wheelchairs for changing occupant posture – Test methods and requirements | N/A |
| ISO 10993-5:2009 | Part 5: Biological Evaluation of Medical Devices – Tests For In Vitro Cytotoxicity | 2-245 |
| ISO 10993-10:2010 | Part 10: Biological Evaluation of Medical Devices – Tests for irritation and skin sensitization | 2-174 |
| EN 1021-1/-2:2014 | Testing of Ignitability For Upholstered Furniture | N/A |
| California Technical Bulletin 117-2013 | Requirements, Test Procedure and Apparatus For Testing The Smolder Resistance Of Materials Used In Upholstered Furniture | N/A |

**Conclusion**

The Modular Power Standing System has similar intended use and similar technological characteristics as the predicate device Levo C3 Power Wheelchair. 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 Standing System has demonstrated that it is as safe, as effective and performs as well as the predicate device.

Therefore, it can be concluded that Modular Power Standing System is substantially equivalent to:

Predicate Device: Levo C3 Power Wheelchair
K083017
Product Code IPL
21 CFR 890.3900