October 28, 2022

Power Plus Mobility
Jason Mohan
CEO President
50 Malcom Rd
Guelph, ON N1K1A9
Canada

Re: K221435
Trade/Device Name: Supertilt Plus (STP)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: February 9, 2022
Received: May 17, 2022

Dear Jason Mohan:

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,

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K221435

Device Name

SUPERTILT PLUS (STP)

Indications for Use *(Describe)*

The intended use for the manual (mechanical) wheelchair is to provide mobility to persons who may be restricted to a sitting position. The manual wheelchair is intended for ongoing daily use. The models offer a wide range of customization which allows for a better fit for the end user resulting in comfort, lightweight, easier propelling, transferring, and smooth ride. The manual wheelchair is intended for indoor and outdoor use on firm surfaces free of climbing obstacles. All other uses are prohibited.

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

Prepared on: 2022-09-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Power Plus Mobility
Applicant Address	50 Malcom Rd Guelph ON N1K1A9 Canada
Applicant Contact Telephone	4168091301
Applicant Contact	Mr. Jason Mohan
Applicant Contact Email	jason@powerplusmobility.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SUPERTILT PLUS (STP)
Common Name	Mechanical wheelchair
Classification Name	Wheelchair, Mechanical
Regulation Number	890.3850
Product Code	IOR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K951138	Concept 45	IOR

Device Description Summary

21 CFR 807.92(a)(4)

A mechanical wheelchair is a chair with wheels, designed to be a replacement for walking, where it is propelled by the seated occupant turning the rear wheels by hand. There are also handles behind the seat for someone else to do the pushing. Wheelchairs are used by people for whom walking is difficult or impossible due to illness, injury, or disability. The device is intended for adults only.

As oppose to the standard wheelchair properties, the Supertilt Tilt main feature can tilt in space for up to 33 degrees using two gas cylinders that can support up to 250 lbs.

The components include frame, back upholstery, seat upholstery, handgrip, armrest, armrest pad, side panel.

In terms of biocompatibility, the main direct contact components on long periods in time with the user/client are the arm rest pad, cushion back cushion, headrest pad and footrest padding. Transient contacts with the user/client include arm skirt guard, arm tube, arm socket and footrest tube.

The Supertilt Plus in its final finished form is identical to the Concept 45, Invacare, K951138, cleared on 3/20/1995 (legally US marketed device) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The intended use for the manual (mechanical) wheelchair is to provide mobility to persons who may be restricted to a sitting position. The manual wheelchair is intended for ongoing daily use. The models offer a wide range of customization which allows for a better fit for the end user resulting in comfort, lightweight, easier propelling, transferring, and smooth ride. The manual wheelchair is intended for indoor and outdoor use on firm surfaces free of climbing obstacles. All other uses are prohibited.

	Proposed Device	Primary Predicate Device
510K Number	K221435	K951138
Product Code	IOR	IOR
Classification Name	Wheelchair, Mechanical	Wheelchair, Mechanical
Model	Supertilt Plus	Concept 45
Manufacturer	Power Plus Mobility Inc.	Invacare Corporation
Indications for Use	The intended use for the manual (mechanical) wheelchair is to provide mobility to persons who may be restricted to a sitting position. The manual wheelchair is intended for ongoing daily use. The models offer a wide range of customization which allows for a better fit for the end user resulting in comfort, lightweight, easier propelling, transferring, and smooth ride. The manual wheelchair is intended for indoor and outdoor use on firm surfaces free of climbing obstacles. All other uses are prohibited.	The intended use for the manual (mechanical) wheelchair is to provide mobility to persons who may be restricted to a sitting position. The manual wheelchair is intended for ongoing daily use. The models offer a wide range of customization which allows for a better fit for the end user resulting in comfort, lightweight, easier propelling, transferring, and smooth ride. The manual wheelchair is intended for indoor and outdoor use on firm surfaces free of climbing obstacles. All other uses are prohibited.
Basic Design	STP is a compact manual wheelchair with 2 gas cylinders that enables tilt-in-space capability, built with a steel frame on 4 wheels, paint covered, with essential accessories as well as back and seating upholstery.	Concept 45 is a compact manual tilt-in-space wheelchair with an optional reclining back.
Materials	Steel (frame, armrest, caster fork, headrest frame, anti-tipper tube, rear axle), aluminum (wheel lock, footrest frame, footplate, handrim, custom headrest ball joint), PVC (armrest pad mount, rear wheel rim and spacers, caster rim, skirt guard), ABS (solid seat)	Steel (frame, armrest, caster fork, rear axle, footrests, headrest frame, wheel lock) aluminum (hand rim). Other materials undocumented
Components	Armrest Rear Axle Rear Wheel Caster Fork Casters Headrest Back Upholstery Seat Seat Upholstery Footrest	Armrest Rear Axle Rear Wheel Caster Fork Casters Headrest Back Upholstery Seat Seat Upholstery Footrest
Occupant Mass Group	III	III
Control Mode	Manual	Manual
Total Mass	60 lbs (Approx.)	55 lbs (Approx.) without front riggings
Weight Capacity	250 lbs	250 lbs
Overall Width	28.45" (regular 18"x18")	23.25"
Overall Length	49.67" (with footrest), 35.39" (with no footrest and retracted spreader bar)	44.75"
Overall Height	39.69" (no headrest), 48.16" (with headrest)	40"
Seat to Floor Height	Adjustable from 12.25" to 18.25", based on various wheel configurations	Adjustable from 14.5" to 18.75"
Tilt Adjustment	0 to 33 degrees	0 to 45 degrees
Recline Tilt Adjustment	0 to 15 degrees of fixed recline adjustment	0 to 20 degrees
Wheel Lock	Aluminum push or pull to lock	Push or pull to Lock
Front Riggings	Swingaway footrest	Swingaway footrests
Rear Axle	Standard (Permanent) or Quick Release	Permanent or Quick Release
Seat Dimensions	18"x18"	15"-20"
Brake Mechanism	Push to Lock or Pull to Lock Wheel Locks	Push to Lock or Pull to Lock Wheel Locks
Front and Rear Wheel Tire Dimensions	6" Caster with 22" Rear Wheel	7" Caster with 22"Rear Wheel
Minimum Curb Clearance	-	Not Publically Available
Curb Climbing Ability	-	Not Publically Available
Minimum Turning Radius	83cm	Not Publically Available
Upholstery Material	Standard Darlex, TEK4 Waterproof at the bottom	Not Publically Available

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use is the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Supertilt Plus has the similar technical characteristics as the predicate device such as tilt and adjustable recline. Both devices have adjustable back angle, arm rest, headrest, as well as similar seat depths and widths.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following testing was performed on the Manual Tilt Wheelchair model STP in accordance with the requirements of the design control regulations and establisthed quality assurance procedures.
ISO 7176-8 - Construction
ISO 7176-14:8 - Design
ISO 7176-5 - Dimensions
ISO 7176-1:9-12 - Stability in Least Stable Configuration
ISO 7176-3:7-1 - Efficiency
ANSI/RESNA WC/Vol.1:22 Annex A - Operation
ISO 7176-15:7, ISO 7176-14:6.1 - Product Literature
ISO 7176-7:8.3 - Angular Dimensions

Power Plus Mobility STP wheelchair was built within the standards of ANSI/RESNA which involves ISO 7176. It is concluded that the STP is safe and effective as well as substantially equivalent to the predicate device.