September 5, 2023

Ki Mobility LLC
Mark Murphy
VP of Operations
5201 Woodward Drive
Stevens Point, Wisconsin 54481

Re: K201869
Trade/Device Name: Ki Power Tilt System
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 21, 2023
Received: August 22, 2023

Dear Mark Murphy:

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 -S

for Heather Dean, PhD
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

Enclosure

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.

510(k) Number *(if known)*
K201869

Device Name
Ki Mobility Power Tilt System

Indications for Use *(Describe)*
The Ki Mobility Power Tilt System kit design is intended for use on a manual wheelchair to provide patients with posterior tilt for positioning and seating pressure relief.

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
K201869

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information

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Date Summary Prepared: August 25, 2023

Name of the Device

Trade Name:	Ki Mobility Power Tilt System
Common Name:	POWERED SEATING TILT SYSTEM FOR MANUAL WHEELCHAIR
Classification Name:	Wheelchair, Powered
Review Panel:	Physical Medicine (PM)
Regulation:	890.3860
Class:	Class II
Product Code:	ITI

Equivalence Claimed to Predicate Device

The Ki Mobility Power Tilt System is equivalent to the TILT MASTER CG SYSTEM (CENTER OF GRAVITY), TILT-N-SPACE-SEAT (K972564), manufactured by MECHANICAL APPLICATION DESIGNS.

Description of the Ki Power Tilt System

The Ki Power Tilt System is an assembly that can be used to provide powered tilt on a manual wheelchair. It is an option for the Focus CR manual wheelchair to allow user control of the seating tilt angle. Ki Mobility is seeking 510K clearance of the Ki Power Tilt System.

The Focus CR provides mobility to adults restricted to a sitting position and features a rotation seat tilt system that reduces translation of the system center of gravity through the tilt range. Angular reposition of the occupant changes the seated pressure distribution, improves comfort, facilitates improved transfer and improves daily activities, such as eating, breathing and social interaction.

The Ki Power Tilt System uses a battery operated motor gear drive connected between the base frame and the rotational seat tilt frame. A curved gear rack is coupled to the rocker frame and driven by the motor gearbox to control tilt motion. The user controls tilt using a toggle switch or hand pendant control connected to the motor control box. Adaptive switches, such as head arrays, may be connected to an interface control box that connects to the control box. Prior 510K clearance K972564 Tilt Master CG System.

The drive motor and switch cables plug into dedicated ports in the control box mounted the wheelchair frame. The toggle switch clamps to the armrest and the lever can be oriented horizontally or vertically. The pendant hand control uses a coiled cable for flexibility in access. Adaptive switches use cables connected to the interface ports. Prior 510K clearance K972564 Tilt Master CG System.

An external battery charger is provided to charge the system. It is connected to a battery cable extension mounted to the frame to allow for easy access and secure connection for charging, with an estimated charge time of 6 hours. The control box will not allow tilt function during charging. Prior 510K clearance K972564 Tilt Master CG System.

The motor control system uses a soft start/soft stop for ramping up and ramping down the motor speed with a current limit to momentarily shut down power supply to the motor. End of travel in the tilt range will engage the current limit and the Focus CR Tilt Stops can be used to limit the tilt range from the unrestricted range of 0º to 50º. Prior 510K clearance K972564 Tilt Master CG System.

The weight capacity of the Focus CR with the Ki Power Tilt System is 300 pounds and has been transit tested for occupied use in a motor vehicle.

Intended Use

The Ki Mobility Power Tilt System kit design is intended for use on a manual wheelchair to provide patients with posterior tilt for positioning and seating pressure relief.

Technological Characteristics to Predicate

The Ki Power Tilt System and TiltMaster CG System have similar techniques of user switch control of 24V battery powered actuators mounted between the wheelchair base frame and the seat frame allowing for change of the seat and back angle frame angle of tilt. The actuators both use worm drive from an electric motor to drive a gear set. The Ki Power Tilt system uses a spur-rack gear system to drive the rotational tilt system, while the TiltMaster CG System uses a lead screw linear drive for a rear pivot tilt system.

Both systems use mechanical systems to hold the drive system in place when the motor is not supplied with current. The Ki Power Tilt System uses a mechanical brake on the drive shaft and TiltMaster CG System uses a clutch on the lead screw.

A primary technological difference lies in the technique of seat tilt. The TiltMaster CG System uses the front lift-rear pivot tilt of the seat frame whereas the Ki Power Tilt System uses a rotational tilt system, which works in combination to the Focus CR.

The Ki Power Tilt System rotational tilt system is inherently safer in the event of a system malfunction in two ways:

1. The motor gear-set allows release of the system drive for readjustment to a desired angle of tilt for continued use.

2. In the event of a failure of the system to hold the tilted seat frame position, the Focus CR tilt system will rotate to a safe intermediate seat tilt angle of 20º whereas a pivot seat tilt will potentially drop under load to 0º.

Performance Data

The Ki Power Tilt System and the predicate TiltMaster CG System are both 24V battery powered seating tilt control systems that are operated by the user with a switch to electronics that control a motor drive of a geared system with mechanical braking to hold the tilted position of the seating system.

The Ki Power Tilt System on the Focus CR with Tilt Stops provides a tilt range of 0 to 50º, versus the -5 to 55º of the TiltMaster CG on the Invacare Storm wheelchair. The tilt range can be adjusted in both systems, using the Tilt Stops in the Focus CR frame and limit switches built into the linear actuator of the TiltMaster CG.

The systems both adapt to wheelchair frames with mounting brackets that maintain the seating size ranges that are available for that wheelchair. The Ki Power Tilt System has a weight limit of 300 pounds on the Focus CR versus the TiltMaster CG Invacare Storm Kit limit of 250 lbs.

A biocompatibility study per ISO 10993 was conducted for the Ki Power Tilt System within a risk analysis framework, with no known biological hazards presented from the materials in contact with the user in operation and is toxicologically safe. Materials primarily consist of aluminum, steel, plastics. A detailed listing of materials is defined in the Biocompatibility report. ISO 10993 sections 1, 5, 10, and 23 are cited in the study.

The Ki Power Tilt System has been successfully tested in combination with a Ki Mobility Focus CR manual wheelchair to the requirements of ISO 7176-30 – Wheelchairs for changing occupant posture – Test method and requirements, including associated testing and report per ISO 7176 sections, 1, 3, 4, 5, 7, 8, 9, 11, 13, 14, 15, 21, 22, 25 and WC-4 Section 19, Wheelchairs used as a seat in motor vehicles.

The TiltMaster CG System does not have publicly available test data for direct comparison of measurements or performance test data. Older versions of ANSI-RESNA and/or ISO standards would have applied to the TiltMaster kits adapted to power wheelchairs such as the Invacare Storm (TiltMaster TK Storm) or manual wheelchair such as the Quickie TS (TiltMaster TK QTS). The requirements of both the ANSI-RESNA & ISO standards have since been revised, with the following chart comparing standards that would have applied in the Mechanical Application Designs, Inc 510(k) TiltMaster CG Systems application and the Ki Power Tilt System.

Revised and new standards serve to increase the safety and efficacy of wheelchair systems with current ANSI-RESNA and ISO standards quite closely harmonized. An exception to this harmonization is ISO 7176-30

Wheelchairs for changing occupant posture – Test methods and requirements, which was released in 2018.The scope of 7176-30 drives test requirements for a tilt-seating wheelchair and compliance verifies performance of the Ki Power Tilt System.

Standards with performance test data applied to Ki Power Tilt System	Standards with performance test data applicable to Tiltmaster CG System
ISO 7176-1:2014	WC/01-1990, ISO 7176-1:1986
ISO 7176-3:2012	WC/03-1990, ISO 7176-3:1988
ISO 7176-4:2008	WC/04-1990, ISO 7176-4:1997
ISO 7176-5:2008	WC/05-1990, ISO 7176-5:1986
ISO 7176-7:1998	WC/07-1991
ISO 7176-8:2014	WC/08-1991
ISO 7176-9:2009	WC/09-1991, ISO 7176-9:1988
ISO 7176-13:1989	WC/13-1991, ISO 717613:1989
ISO 7176-14:2008	WC/14-1991, ISO 7176-14:1997
ISO 7176-21:2009	NA in 1997
ISO 7176-25:2013	NA in 1997
ISO 7176-30:2018	NA in 1997
WC-4:2017 Section 19	NA in 1997

Conclusions

The Ki Power Tilt System can be concluded to be substantially equivalent to its predicate device K972564 TiltMaster CG System based on the same intended use, scope of operation, and same technological characteristics and comparable performance data per standards, with no safety and effectiveness issues raised. Methods used to evaluate include engineering performance testing and biocompatibility evaluation.