November 19, 2021

Magic Mobility
℅ Matthieu Kirkland
Regulatory Specialist
Acknowledge Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K213090
Trade/Device Name: Frontier Series Power Wheelchairs
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 20, 2021
Received: September 24, 2021

Dear Matthieu Kirkland:

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,

Heather L. Dean -S

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)*
K213090

Device Name
Frontier Series Power Wheelchairs

Indications for Use *(Describe)*
The Frontier Series Power Wheelchairs are battery-operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.

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

DATE PREPARED
September 20, 2021

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Frontier Series Power Wheelchairs
Common Name:	Wheelchair, Powered
Regulation Number:	21 CFR 890.3860
Class:	Class II
Product Code:	ITI
Premarket Review:	Neuromodulation and Physical Medicine Devices (DHT5B)
Review Panel:	Physical Medicine

PREDICATE DEVICE IDENTIFICATION
The Frontier Series Power Wheelchairs are substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate Relationship*
K030783	Frontier Power Wheelchair/ Innovation In Motion	Primary Predicate Device
K142457	Quickie® and Zippie® Powered Wheelchairs / Sunrise Medical (US) LLC	Secondary Predicate Device
K172384	Quickie® Q700-UP M / Sunrise Medical (US) LLC	Reference Device

DEVICE DESCRIPTION

The Frontier Series Power Wheelchairs have four configurations: V4 RWD, V4 FWD, V6, and C73. The Frontier Series Power Wheelchairs are designed for everyday use for both indoor and outdoor environments including care facilities and private residences. The subject devices are intended to provide mobility to persons who are restricted or limited to a sitting position.

The Frontier Series Power Wheelchairs are battery powered, electric motor driven devices that can be used on both indoor and outdoor surfaces (i.e., concrete, asphalt, indoor flooring such as carpet, gravel, grass, and bark/woodchips).

The Frontier Series Power Wheelchairs include the following accessories:

- Extra spreader bar
- Slide in table
- Lights
- Luggage rack
- Accessory charger
- Posture belt
- Roho cushion
- Jay cushion
- MPS push rail
- MPS peg push handle
- Scooter stopper
- Retractable docking pin
- Fold forward kit

INTENDED USE

Magic Mobility power chairs are designed for the exclusive use of people (adults and children) who are unable to walk or have limited mobility and have the cognitive, physical and visual ability to control the vehicle safety. The Magic Mobility Frontier series is intended to be self-propelled on a range of surfaces. The All-Terrain tires can be used on both indoor and outdoor surfaces (i.e., concrete, asphalt, indoor flooring such as carpet, gravel, grass, and bark/woodchips).

INDICATIONS FOR USE

The Frontier Series Power Wheelchairs are battery-operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Magic Mobility believes that the Frontier Series Power Wheelchairs are substantially equivalent to the predicate devices based on the information summarized here:

The subject devices have a similar design and dimensions and uses similar or identical materials as the devices cleared in K030783 and K142457. The subject devices have the same intended use and similar technological characteristics (i.e., base technology and OEM joystick control) to the devices cleared in K030783, K142457, and K172384. The subject devices have the same intended use environment, including off road capabilities, as the device cleared in K030783. The subject devices use the same software as the device cleared in K172384. The Frontier Series Power Wheelchairs have undergone testing to ensure that any differences in technological characteristics (i.e., battery, castor wheels, and no anti-pitch mechanism) do not affect safety and effectiveness when compared to the predicate and reference devices.

	Subject Devices	Predicate Device	Predicate Device	Reference Device	Statement of Equivalence
	Magic Mobility Frontier Series Power Wheelchairs	Innovation in Motion Frontier Power Wheelchair K030783	Sunrise Medical (US) LLC Quickie® and Zippie® Powered Wheelchairs K142457	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
Indications for Use	The Frontier Series Power Wheelchairs are battery-operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.	The intended use of the Frontier Power wheelchair is to provide mobility to persons limited to a sitting position, who have the capability of operating a power wheelchair.	Quickie® and Zippie® power wheelchairs are battery-operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position. The Zippie® power wheelchairs are specifically for people who are slightly smaller in stature—including children.	The Sunrise Medical Quickie® Q700-UP M power wheelchairs are battery operated devices, that are indicated for medical purposes to provide mobility and repositioning of the user, including a stand-up feature.	Substantially equivalent to predicate devices.
Product Codes / Regulation Number	ITI /21 CFR 890.3860	ITI / 21 CFR 890.3860	ITI / 21 CFR 890.3860	IPL / 21 CFR 890.3900	Identical to the primary predicate. No impact on safety and effectiveness.
Regulation Description	Powered Wheelchair	Powered Wheelchair	Powered Wheelchair	Standup Wheelchair	Identical to the primary predicate. No impact on safety and effectiveness.
Technical Specifications					
General					
Maximum User Weight (lbs)	Frontier V4 FWD: 400 Frontier V4 RWD: 400 Frontier V6: 400 Frontier V6 C73:400	400	300	265	Identical to the primary predicate. No impact on safety and effectiveness.
Storage Temperature (ºC)	-40 to 70	-40 to 70	-40 to 70	-40 to 70	Identical to the primary predicate. No impact on safety and effectiveness.
Location for Use	Indoors and outdoors including care facilities, and residences	Indoors and outdoors including care facilities, and residences	Indoors and outdoors including care facilities, and residences	Indoors and outdoors including care facilities, and residences	Identical to the primary predicate. No impact on safety and effectiveness.
Frame Material	Steel	Steel	Steel and aluminum	Steel and aluminum	Identical to the primary predicate.

	Subject Devices	Predicate Device	Predicate Device	Reference Device	Statement of Equivalence
	Magic Mobility Frontier Series Power Wheelchairs	Innovation in Motion Frontier Power Wheelchair K030783	Sunrise Medical (US) LLC Quickie® and Zippie® Powered Wheelchairs K142457	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
					No impact on safety and effectiveness.
Biocompatibility	Uses materials common to many wheelchairs	Uses materials common to many wheelchairs	Uses materials common to many wheelchairs	Uses materials common to many wheelchairs	Identical to the primary predicate. No impact on safety and effectiveness.
Base					
Overall Dimensions (length by width; inches)	Frontier V4 FWD AT tires: 39.2 x28 Frontier V4 FWD Hybrid tires: 39.2 x 26.3 Frontier V4 RWD AT tires: 36.6 x 28 Frontier V4 RWD Hybrid tires: 36.6 x 26.3 Frontier V6 AT tires: 42 x 28 Frontier V6 Hybrid tires: 42 x 27.5 Frontier V6 C73: 39.5 x 25.5	43.34 x 28	24”x34”	25”x36”	Substantially equivalent to the predicate and reference devices. No impact on safety and effectiveness.
Rolling Base Weight (lbs)	Frontier V4 FWD: 210 (with batteries) Frontier V4 RWD: 210 (with batteries) Frontier V6: 220 (with batteries) Frontier V6 C73: 220 (with batteries)	260 (with batteries)	130	152	Substantially equivalent to the predicate device. No impact on safety and effectiveness.
Power Source	Batteries	Batteries	Batteries	Batteries	Identical to the primary predicate. No impact on safety and effectiveness.

	Subject Devices	Predicate Device	Predicate Device	Reference Device	Statement of Equivalence
	Magic Mobility Frontier Series Power Wheelchairs	Innovation in Motion Frontier Power Wheelchair K030783	Sunrise Medical (US) LLC Quickie® and Zippie® Powered Wheelchairs K142457	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
Battery Details	Two (2) 73 Ahr	Two (2) 73 Ahr	22 NF, sealed lead acid or gel cell	24V (2x12V) / 73 Ah/20h	Identical to the primary predicate. No impact on safety and effectiveness.
Castor Wheel Size (inches)	8.25 x 2.5	8.25 x 2.5	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.
Range (miles)	15-20	15-20	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.
Anti-pitch Mechanism for Climbing	None	None	Additional anti-pitch lock out	Additional anti-pitch lock out	Identical to the primary predicate. No impact on safety and effectiveness.
Lift Range (inches)	0-12	0-12	0-12	0-12	Identical to the primary predicate. No impact on safety and effectiveness.
Tilt Range (degrees)	0-50	0-50	0-50	0-50	Identical to the primary predicate. No impact on safety and effectiveness.
Recline Range (degrees)	0-170	0-170	0-170	0-172	Identical to the primary predicate. No impact on safety and effectiveness.
Suspension	Independent drive wheel suspension with shock absorber on pivoting swing arm and articulated castors to ensure all wheels maintain adhesion at all surface angles	Independent drive wheel suspension with shock absorber on pivoting swing arm and articulated castors to ensure all wheels maintain adhesion at all surface angles	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.
Maximum speed (mm)	6	6	6	6 (with an option of 8)	Identical to the primary predicate. No impact on safety and effectiveness.

	Subject Devices	Predicate Device	Predicate Device	Reference Device	Statement of Equivalence
	Magic Mobility Frontier Series Power Wheelchairs	Innovation in Motion Frontier Power Wheelchair K030783	Sunrise Medical (US) LLC Quickie® and Zippie® Powered Wheelchairs K142457	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
Minimum Braking Distance at Maximum Speed (meters)	1.8	1.8	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.
User Controller	Joystick and hand control buttons	Joystick and hand control buttons	Joystick and hand control buttons	Joystick and hand control buttons	Identical to the primary predicate. No impact on safety and effectiveness.
Joystick Mount	Joystick and hand control buttons	Joystick and hand control buttons	Fixed mount, height adjustable, swing-away	Fixed mount, height adjustable, swing-away	Identical to the primary predicate. No impact on safety and effectiveness.
Software					
Software	R-Net from PGDT	R-Net from PGDT	VR2 from PGDT	R-Net from PGDT	Identical to the predicate and reference devices. No impact on safety and effectiveness.
Seat/Armrest/Footrest					
Seat Height (minimum, inches)	17.1	17.1	16.2	16.2”	Identical to the primary predicate. No impact on safety and effectiveness.
Seat Width (inches)	16-24	16-24	12-24	16-22	Identical to the primary predicate. No impact on safety and effectiveness.
Armrest	Height adjustable, Removable, flip up option	Height adjustable, Removable, flip up option	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.
Footrest	Rigid footplate, flip up nylon	Rigid footplate, flip up nylon	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate substantial equivalence based on current industry and FDA recognized standards. The results of these tests indicate that the Frontier Series Power Wheelchairs are substantially equivalent to the predicate devices.

PERFORMANCE

- Static stability (per ISO 7176-1)
- Dynamic stability (per ISO 7176-2)
- Effectiveness of brakes (per ISO 7176-3)
- Energy consumption (per ISO 7176-4)
- Dimensions, mass, and maneuvering space (per ISO 7176-5)
- Maximum speed, acceleration, and deceleration (per ISO 7176-6)
- Measurement of seat and wheel dimensions (per ISO 7176-7)
- Static, impact, and fatigue (per ISO 7176-8)
- Climatic test (per ISO 7176-9)
- Obstacle climbing (per ISO 7176-10)
- Test dummies (per ISO 7176-11)
- Power and control systems for power wheelchairs (per ISO 7176-14)
- Documentation and labeling (per ISO 7176-15)
- Resistance to ignition (per ISO 7176-16)
- Dynamic Test (per ISO 71716-19)
- Vocabulary (per ISO 7176-26)

EMC AND ELECTRICAL SAFETY

- EMC testing (per ISO 7176-21)
- Batteries and chargers per (per ISO 7176-25)

BIOCOMPATIBILITY

- Evaluation and testing within a risk management process (per ISO 10993-1)
- *In vitro* cytotoxicity (per ISO 10993-5)

The materials used in the subject devices are identical in chemical composition, formulation processing, sterilization, and geometry as the materials found in the devices cleared in K030783, K142457, and K172384 . Furthermore, the Frontier Series Power Wheelchairs have the same nature of tissue contact and contact duration as the predicate and reference devices. Therefore, based on previous use and the cytotoxicity testing conducted, the subject devices are considered to have met the requirements of ISO 10993-1 and FDA's Guidance for Industry and Food and Drug Administration Staff – Use of International ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

SOFTWARE

- Software life cycle process (per IEC 62304)

CONCLUSION

Based on the testing performed (including wheelchair dynamic testing and flammability) it can be concluded that the subject devices do not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Frontier Series Power Wheelchairs are assessed to be substantially equivalent to the predicate devices.