March 4, 2024

Magic Mobility
% Pierre Bounaud
Principal Consultant
Rqm+
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K233877
Trade/Device Name: XT Series Power Wheelchair (XT2), XT Series Power Wheelchair (XT4)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: November 26, 2023
Received: December 7, 2023

Dear Pierre Bounaud:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Rehabilitation 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)*
K233877

Device Name
XT Series Power Wheelchair (XT2);
XT Series Power Wheelchair (XT4)

Indications for Use *(Describe)*
The XT2 power wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.
The XT4 power wheelchair is a battery-operated device with wheels that is 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
K233877

K233877
510(k) SUMMARY

DATE PREPARED
November 26, 2023

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DEVICE INFORMATION

Proprietary Name/Trade Name:	XT Series Power Wheelchair (XT2 and XT4 models)
Common Name:	Powered wheelchair
Regulation Number:	21 CFR 890.3860
Class:	II
Product Code:	ITI
Premarket Review:	OHT5/Neuromodulation and Physical Medicine Devices (DHT5B)
Review Panel:	Physical Medicine

PREDICATE DEVICE IDENTIFICATION
The XT Series Power Wheelchair is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Device*
K211574	Extreme X8 / Magic Mobility	✓	
K172384	Quickie® Q700-UP M / Sunrise Medical (US) LLC		✓

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The XT Series Power Wheelchair has two configurations: XT2 and XT4. They are designed for everyday use for both indoor and outdoor environments including care facilities and private residences. The subject device is intended to provide mobility to persons who are restricted or limited to a sitting position.

The XT 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 XT Series Power Wheelchair offers two basic seating options: MPS and Rehab. The MPS option is more static and does not allow for additional aftermarket cushions. The Rehab option is more adjustable to adhere to recommendations from the user's physician or physical therapist.

The XT 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
- 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 safely. The XT Series Power Wheelchairs are intended to be self-propelled on a range of surfaces and 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 XT2 power wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.
The XT4 power wheelchair is a battery-operated device with wheels that is 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 XT Series Power Wheelchair is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar or identical materials as the devices cleared in K211574. The subject device has the same intended use and similar technological characteristics (i.e., base technology and OEM joystick control) to the devices cleared in K211574 and K172384. The subject device has the same intended use environment, including off road capabilities, as the device cleared in K211574. The subject device uses the same software as the device cleared in K211574 and K172384. The Magic XT Series Power Wheelchairs have undergone testing to ensure that any differences in technological characteristics (i.e., battery size, frame design) do not affect safety and effectiveness when compared to the predicate devices.

	Subject Device	***Predicate Device***	***Reference Device***	Statement of Equivalence
	Magic Mobility XT Series Power Wheelchair K233877	Magic Mobility Extreme X8 Power Wheelchair K211574	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
Indications for Use	The XT2 power wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair. The XT4 power wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.	The Extreme X8 Power Wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position who have the capability of operating a power wheelchair.	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.	Identical to predicate device. No impact on safety or effectiveness.
Product Code / Regulation Number	ITI / 21 CFR 890.3860	ITI / 21 CFR 890.3860	IPL / 21 CFR 890.3900	Identical to predicate device. No impact on safety and effectiveness.
Regulation Description	Powered Wheelchair	Powered Wheelchair	Standup Wheelchair	Identical to predicate device. No impact on safety and effectiveness.
Maximum User Weight (lbs)	XT2: 300 XT4: 400	400	265	Similar to predicate device. No impact on safety and effectiveness.
Storage Temperature (ºC)	-40 to 70ºC	-40 to 70ºC	-40 to 70ºC	Identical to predicate and reference devices. No impact on safety and effectiveness.
Location for Use	Indoors and outdoors including care facilities, residences, and soft/rough terrain	Indoors and outdoors including care facilities, residences, and soft/rough terrain	Indoors and outdoors including care facilities, and residences	Identical to predicate and reference devices. No impact on safety and effectiveness.
Frame Material	Steel	Steel	Steel and aluminum	Identical to predicate and reference devices. 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	Identical to predicate and reference devices. No impact on safety and effectiveness.
Ground Clearance	5”	4”	Unknown	Similar to predicate device. No impact on safety and effectiveness.

	Subject Device	***Predicate Device***	***Reference Device***	Statement of Equivalence
	Magic Mobility XT Series Power Wheelchair K233877	Magic Mobility Extreme X8 Power Wheelchair K211574	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
Overall Dimensions (length by width; inches)	XT2: 43.5" x 27" XT4: 39.5"x 27.5"	45.25" x 27"	25" x 26"	Similar to predicate device. No impact on safety and effectiveness.
Rolling Base Weight (lbs)	XT2: 167 XT4: 183	145	152	Similar to predicate device. No impact on safety and effectiveness.
Power Source	Batteries	Batteries	Batteries	Identical to predicate and reference devices. No impact on safety and effectiveness.
Battery Details	2- Group 31 12-volt AGM or Gel 20h capacity in 95-115 AMP/hour range.	2- 73 AMP/hour AGM Group 24 12-volt Weight 55 lbs	24V (2x12V) / 73 Ah/20h	Similar to predicate device. No impact on safety and effectiveness.
Battery Charger Input Voltage (volts)	110	110	Unknown	Identical to predicate device. No impact on safety and effectiveness.
Motors	XT2: 2 motors XT4: 4 motors 24V, 4 pole direct drive gear in line motors/gearbox. Freewheeling lever/motor lock releases & engages motor brakes	4-24V, 4 pole direct drive gear in line motors/gearbox. Freewheeling lever/motor lock releases & engages rear motor brakes	Unknown	Similar to predicate device. No impact on safety and effectiveness.
Wheel Size (inches)	4" x 14"	4" x 14"	Unknown	Identical to predicate device. No impact on safety and effectiveness.
Turning Radius (inches)	XT2: 69" XT4: 55.5"	52"	Unknown	Similar to predicate device. No impact on safety and effectiveness.
Range (miles)	XT2: 33 XT4: 24	15.5	Unknown	Similar to predicate device. No impact on safety and effectiveness.
Maximum Speed (mph)	6.2	6.2	6 (with an option of 8)	Identical to predicate device. No impact on safety and effectiveness.
Anti-pitch Mechanism for Climbing	None	None	Additional anti-pitch lock out	Identical to predicate device. No impact on safety and effectiveness.
Lift Range (inches)	0-12"	0-12"	0-12"	Identical to predicate device. No impact on safety and effectiveness.
Tilt Range (degrees)	0-50	0-50	0-50	Identical to predicate device. No impact on safety and effectiveness.

	Subject Device	***Predicate Device***	***Reference Device***	Statement of Equivalence
	Magic Mobility XT Series Power Wheelchair K233877	Magic Mobility Extreme X8 Power Wheelchair K211574	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	
Recline Range (degrees)	0-170	0-170	0-172	Identical to predicate device. No impact on safety and effectiveness.
Suspension	Front and Rear	None	Unknown	Similar to predicate device. No impact on safety and effectiveness.
Braking System	Electromagnetic, regenerative brakes with a free-wheeling mode	Electromagnetic, regenerative brakes with a free-wheeling mode	Unknown	Identical to predicate device. No impact on safety and effectiveness.
Minimum Braking Distance at Maximum Speed (meters)	1.7	1.7	Unknown	Identical to predicate device. No impact on safety and effectiveness.
User Controller	Joystick and hand control buttons	Joystick and hand control buttons	Joystick and hand control buttons	Identical to predicate device. No impact on safety and effectiveness.
Joystick Mount	Fixed mount, height adjustable, swing-away	Fixed mount, height adjustable, swing-away	Fixed mount, height adjustable, swing-away	Identical to predicate device. No impact on safety and effectiveness.
Software	R-Net from PGDT	R-Net from PGDT	R-Net from PGDT	Identical to predicate device. No impact on safety and effectiveness.
Seat Height (minimum, inches)	19”	19”	16.2”	Identical to predicate device. No impact on safety and effectiveness.
Seat Width (inches)	12”-24”	16”-24”	16”-22”	Similar to predicate device. No impact on safety and effectiveness.
Armrest	Height adjustable, removable, flip up option	Height adjustable, removable, flip up option	Unknown	Identical to predicate device. No impact on safety and effectiveness.
Footrest	1 or 2 pieces, fixed or flip up, angle and height adjustable rigid footplates, and others	1 or 2 pieces, fixed or flip up, angle and height adjustable rigid footplates, and others	Unknown	Identical to predicate device. 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 XT Series Power Wheelchair is substantially equivalent to the predicate device.

BENCH TESTING	
ISO 7176-1	Static stability
ISO 7176-2	Dynamic stability
ISO 7176-3	Effectiveness of brakes
ISO 7176-4	Energy consumption
ISO 7176-5	Dimensions, mass, and maneuvering space
ISO 7176-6	Maximum speed, acceleration, and deceleration
ISO 7176-7	Measurement of seat and wheel dimensions
ISO 7176-8	Static, impact, and fatigue
ISO 7176-9	Climatic test
ISO 7176-10	Obstacle climbing
ISO 7176-11	Test dummies
ISO 7176-14	Power and control systems for power wheelchairs
ISO 7176-15	Documentation and labeling
ISO 7176-16	Resistance to ignition
ISO 7176-19	Dynamic Test
ISO 7176-26	Vocabulary
ISO 7176-30	Wheelchairs for changing occupant posture

EMC AND ELECTRICAL SAFETY	
ISO 7176-21	EMC testing
ISO 7176-25	Batteries and chargers

BIOCOMPATIBILITY	
ISO 10993-1	Evaluation and testing within a risk management process

The materials used in the subject device are identical in chemical composition, formulation processing, and geometry as the materials found in the Extreme X8 Power Wheelchair by Magic Mobility LLC (K211574) and the Quickie Q700-UP M by Sunrise Medical (US) LLC (K172384) device. Furthermore, the T Series Power Wheelchair has the same type and duration of patient contact as the predicate and reference devices. Therefore, based on previous use, the subject device is 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	
IEC 62304	Software life cycle process

The results of these tests indicate that the XT Series Power Wheelchair is substantially equivalent to the predicate devices.

CONCLUSION

Based on the testing performed (including wheelchair dynamic testing and flammability) it can be concluded that the subject device does 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 XT Series Power Wheelchair are assessed to be substantially equivalent to the predicate device.