July 9, 2021

Magic Mobility
% Michelle Rubin-Onur
Senior Regulatory Specialist
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave
Suite B-257
San Diego, California 92110

Re: K211574
Trade/Device Name: Extreme X8 Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 20, 2021
Received: May 21, 2021

Dear Michelle Rubin-Onur:

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 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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K211574

Device Name
Extreme X8 Power Wheelchair

Indications for Use *(Describe)*
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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

**K211574**

**DATE PREPARED**

July 9, 2021

**MANUFACTURER AND 510(k) OWNER**

Magic Mobility
3 International Court, Scoresby, VIC, 3179 Australia
Telephone: +61 3 8791 5600
Official Contact: Alex Suen, Quality Assurance and Regulatory Affairs Manager

**REPRESENTATIVE/CONSULTANT**

Michelle Rubin-Onur, Ph.D.
Matthieu Kirkland, M.S.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: mrubin@acknowledge-rs.com

**DEVICE INFORMATION**

| | |
|---|---|
| Proprietary Name/Trade Name: | Extreme X8 Power Wheelchair |
| 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 Extreme X8 Power Wheelchair is substantially equivalent to the following predicates:

| *510(k) Number* | *Predicate Device Name / Manufacturer* | *Predicate Relationship* |
|---|---|---|
| K090350 | Extreme 4x4-X8 / Innovation In Motion | Predicate Device |
| K172384 | Quickie® Q700-UP M / Sunrise Medical (US) LLC | Reference Device |

**DEVICE DESCRIPTION**

The Extreme X8 Power Wheelchair is 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 Extreme X8 Power Wheelchair is a battery powered, electric motor driven device 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 Extreme X8 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 Extreme X8 Power Wheelchair includes 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
- Steering lock

**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 Extreme X8 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 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.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

Magic Mobility believes that the Extreme X8 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 device cleared in K090350. 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 K093050 and K172384. The subject device has the same intended use environment, including off road capabilities, as the device cleared in K090350. The subject device uses the same software as the device cleared in K172384. The Extreme X8 Power Wheelchair has 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 device.

| | ***Subject Device*** | ***Predicate Device*** | ***Reference Device*** | |
|---|---|---|---|---|
| | Magic Mobility<br><br>Extreme X8 Power Wheelchair | Innovation In Motion<br><br>Extreme 4x4-X8<br><br>K090350 | Sunrise Medical (US) LLC<br><br>Quickie® Q700-UP M<br><br>K172384 | Statement of Equivalence |
| **Indications for Use** | 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 intended use of the X8 power wheelchair is to provide mobility to persons limited 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 Codes / 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. |
| **Technical Specifications** | | | | |
| General | | | | |
| **Maximum User Weight (lbs.)** | 400 | 400 | 265 | Identical to predicate device. No impact on safety and effectiveness. |
| **Storage Temperature (ºC)** | -40 to 70ºC | -40 to 70ºC | -40 to 70 | 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, and residences | 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** | 4” | 4” | Unknown | Identical to predicate device. No impact on safety and effectiveness. |
| **Base** | | | | |
| **Overall Dimensions (length by width; inches)** | 45.25”x37” | 45.25”x37” | 25”x36” | Identical to predicate device. No impact on safety and effectiveness. |

| | ***Subject Device*** | ***Predicate Device*** | ***Reference Device*** | |
|---|---|---|---|---|
| | Magic Mobility<br><br>Extreme X8 Power Wheelchair | Innovation In Motion<br><br>Extreme 4x4-X8<br><br>K090350 | Sunrise Medical (US) LLC<br><br>Quickie® Q700-UP M<br><br>K172384 | Statement of Equivalence |
| **Rolling Base Weight (lbs.)** | 145 | 145 | 152 | Identical 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- 73 AMP/hour AGM Group 24 12-volt Weight 55 lbs | 2- 73 AMP/hour AGM Group 24 12 volt Weight 55 lbs | 24V (2x12V) / 73 Ah/20h | Identical 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** | 4-24V, 4 pole direct drive gear in line motors/gearbox. Freewheeling lever/motor lock releases & engages rear motor brakes | 4-24V, 4 pole direct drive gear in line motors/gearbox. Freewheeling lever/motor lock releases & engages rear motor brakes | Unknown | Identical to predicate device. No impact on safety and effectiveness. |
| **Wheel Size (inches)** | 4”x14” | 4”x14” | Unknown | Identical to predicate device. No impact on safety and effectiveness. |
| **Turing Radius (inches)** | 52” | 52” | Unknown | Identical to predicate device. No impact on safety and effectiveness. |
| **Range (miles)** | 15.5 | 15.5 | Unknown | Identical 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. |
| **Recline Range (degrees)** | 0-170 | 0-170 | 0-172 | Identical to predicate device. No |

| | ***Subject Device*** | ***Predicate Device*** | ***Reference Device*** | |
|---|---|---|---|---|
| | Magic Mobility<br><br>Extreme X8 Power Wheelchair | Innovation In Motion<br><br>Extreme 4x4-X8<br><br>K090350 | Sunrise Medical (US) LLC<br><br>Quickie® Q700-UP M<br><br>K172384 | Statement of Equivalence |
| | | | | impact on safety and effectiveness. |
| **Suspension** | None | None | Unknown | Identical 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** | | | | |
| **Software** | R-Net from PGDT | Dynamic DX2-PMA70L electronic control and joystick | R-Net from PGDT | Identical to reference device. No impact on safety and effectiveness. |
| **Seat/Armrest/Footrest** | | | | |
| **Seat Height (minimum, inches)** | 19” | 19” | 16.2” | Identical to predicate device. No impact on safety and effectiveness. |
| **Seat Width (inches)** | 16”-24” | 16”-24” | 16”-22” | Identical 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 Extreme X8 Power Wheelchair is substantially equivalent to the predicate device.

**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 device are identical in chemical composition, formulation processing, sterilization, and geometry as the materials found in the Extreme 4x4-X8 Power Wheelchair by Magic Mobility LLC (K090350) and the Quickie Q700-UP M by Sunrise Medical (US) LLC (K172384) device. Furthermore, the Extreme X8 Power Wheelchair has 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 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**

- 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 device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed Extreme X8 Power Wheelchair are assessed to be substantially equivalent to the predicate device.