March 17, 2021

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

Re: K203083
Trade/Device Name: Magic 360 Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 17, 2020
Received: December 18, 2020

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)*
K203083

Device Name
Magic 360 Power Wheelchair

Indications for Use *(Describe)*
The Magic 360 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
K203083

DATE PREPARED
March 17, 2020

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Magic 360 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 Magic 360 Power Wheelchair is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate Relationship*
K142457	Quickie® and Zippie® Powered Wheelchairs / Sunrise Medical (US) LLC	Primary Predicate
K181908	Action Trackchair: Eagle 16, Eagle 18, Eagle 20, Eagle 22, Eagle 24 / Action Manufacturing Inc.	Secondary Predicate
K172384	Quickie® Q700-UP M / Sunrise Medical (US) LLC	Reference Device

DEVICE DESCRIPTION

The Magic 360 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 that are restricted or limited to a sitting position.

The Magic 360 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, gravel, grass, and bark). The subject device has two seat options: MPS and rehab. The rehab seat option has more built-in adjustments (i.e., width and depth adjustments) and allows for aftermarket cushions. All the wheelchairs include the same power seating options including lift, tilt, recline, and leg elevation to ensure the user to find a position that is comfortable.

The Magic 360 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

Please note, the fold forward kit is an accessory which allows the user to fold the wheelchair and put the wheelchair in a car. To fold the wheelchair the user pulls the red release handle located at the back of the Magic 360 Power Wheelchair. To unfold the wheelchair the user pulls the frame back into place using the armrests.

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. Users must have the cognitive, physical and visual ability to control the vehicle safely. The Magic Mobility Magic 360 power chair is intended to be self-propelled on a range of surfaces that vary depending on the configuration of the chair: Urban, Off-Road, and Crossover. The Urban configuration with narrow tires is better suited for tighter spaces and harder surfaces such as all traditional interior surfaces

(e.g., carpet, laminate and tile flooring) and hard outdoor surfaces (e.g., concrete, asphalt, and tarmac). The Urban configurations are not designed for unstable, inconsistent, or loose surfaces such as grass, loose stone, sand, or cobblestone. The Off-Road configuration with wider tires is physically larger requiring more space to maneuver, however, it is well suited on surfaces such as grass, loose stone, sand, or cobblestone. The Crossover is a compromise between the Urban and Off-Road configurations.

INDICATIONS FOR USE

The Magic 360 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 Magic 360 Power Wheelchair is substantially equivalent to the predicate devices 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 K142457. The subject devices have the same intended use and similar technological characteristics (e.g., base technology and OEM joystick control) to the devices cleared in K142457. The subject device has the same intended use environment, including off-road, as the device cleared in K181908. The subject devices use the same software as the device cleared in K172384. The Magic 360 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 devices.

	Subject Device	***Primary Predicate Device***	***Predicate Device***	***Reference Device***	
	Magic Mobility Magic 360 Power Wheelchair	Sunrise Medical (US) LLC Quickie® and Zippie® Powered Wheelchairs K142457	Action Manufacturing, Inc. Action Trackchair: Eagle 16, Eagle 18, Eagle 22, Eagle 21 K181908	Sunrise Medical (US) LLC Quickie® Q700-UP M K172384	Statement of Equivalence
Indications for Use	The Magic 360 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.	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 Action Trackchair all-terrain power wheelchair provides mobility to individuals who need a power wheelchair, that are capable of operating a powered wheelchair and are limited to a seated position. The Action Trackchair does not require a doctor's prescription.	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 primary predicate. No impact on safety or effectiveness.
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 primary and secondary predicate. No impact on safety and effectiveness.
Regulation Description	Powered Wheelchair	Powered Wheelchair	Powered Wheelchair	Standup Wheelchair	Identical to primary and secondary predicate. No impact on safety and effectiveness.
Technical Specifications					
General					
Maximum User Weight (lbs)	300	300	400	265	Identical to primary predicate. No impact on safety and effectiveness.

	Subject Device	***Primary Predicate Device***	***Predicate Device***	***Reference Device***	
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Storage Temperature (ºC)	-40 to 70	-40 to 70	Unknown	-40 to 70	Identical to primary 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, 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 and aluminum	Steel and aluminum	Unknown	Steel and aluminum	Identical to primary 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	Uses materials common to many wheelchairs	Identical to predicate and reference devices. No impact on safety and effectiveness.
Maximum Speed (mph)	6	6	3	6 (with an option of 8)	Identical to primary predicate. No impact on safety and effectiveness.
Base					
Overall Dimensions (length by width)	26”x38.7”	24”x34”	42”x52.5”	25”x36”	Substantially equivalent to the predicate and reference devices. No impact on safety and effectiveness.
Rolling Base Weight (lbs)	130	130	Unknown	152	Identical to primary predicate. No impact on safety and effectiveness.
Power Source	Batteries	Batteries	Batteries	Batteries	Identical to predicate

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						and reference devices. No impact on safety and effectiveness.
Battery Details		24V (2x12V) / 73 Ah/20h	22 NF, sealed lead acid or gel cell	24 V (2x12V)	24V (2x12V) / 73 Ah/20h	Identical to secondary predicate and reference devices. No impact on safety and effectiveness.
Drive Wheel Diameter (inches)		14	13	Unknown	14	Identical to reference device. No impact on safety and effectiveness.
Castor Wheel Size (inches)	**Front**	8	7	Unknown	6	Substantially equivalent to the primary predicate and reference devices. No impact on safety and effectiveness.
	Rear	8”	6	Unknown	6	Substantially equivalent to the primary predicate and reference devices. No impact on safety and effectiveness.
Anti-pitch Mechanism for Climbing		None	Additional anti-pitch lock out	Unknown	Additional anti-pitch lock out	Substantially equivalent to the primary predicate and reference devices. No impact on safety and effectiveness.
Range (miles)		22.5	Unknown	10	Unknown	Substantially equivalent to the predicate and reference devices. No impact on safety and

	Subject Device	***Primary Predicate Device***	***Predicate Device***	***Reference Device***	
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					effectiveness.
Lift Range (inches)	0-12	0-12	Unknown	0-12	Identical to primary predicate and reference devices. No impact on safety and effectiveness.
Tilt Range (degrees)	0-50	0-50	20 (forward and back)	0-50	Identical to primary predicate and reference devices. No impact on safety and effectiveness.
Recline Range (degrees)	0-170	0-170	Unknown	0-172	Identical to primary predicate and reference devices. No impact on safety and effectiveness.
Suspension	Independent drive wheel suspension with shock absorbers	Standard all wheel suspension with shock absorbers	Unknown	Suspension lock system	Substantially equivalent to the primary predicate and reference devices. No impact on safety and effectiveness.
Type of Braking System	Electromagnetic, regenerative brakes with a free-wheeling mode	Electromagnetic	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	Joystick and hand control buttons	Identical to primary predicate and reference devices. No impact on safety and effectiveness.
Joystick Mount	Fixed mount, height adjustable, swing-away	Fixed mount, height adjustable, swing-away	Unknown	Fixed mount, height adjustable, swing-away	Identical to primary predicate and reference devices. No impact on safety and effectiveness.

	Subject Device	***Primary Predicate Device***	***Predicate Device***	***Reference Device***	
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Folding mechanism	Yes (fold forward kit accessory)	Yes (fold down backrest)	Unknown	Unknown	Substantially equivalent to the primary predicate. No impact on safety and effectiveness.
Software					
Software	R-Net from PGDT	VR2 from PGDT	Unknown	R-Net from PGDT	Identical to reference device. No impact on safety and effectiveness.
Seat/Armrest/Footrest					
Seat Height (minimum, inches)	17.1	16.2	23	16.2	Substantially equivalent to the predicate and reference devices. No impact on safety and effectiveness.
Seat Width (inches)	12-22	12-24	Unknown	16-22	Substantially equivalent to the primary predicate and reference devices. No impact on safety and effectiveness.
Armrest	Height adjustable, removable, flip up option	Height adjustable and flip up option	Unknown	Unknown	Identical to the primary predicate. No impact on safety and effectiveness.
Footrest	1 or 2 pieces, fixed or flip up, angle and height adjustable rigid footplates	Swing away footrests with heel loops	Height adjustable	Unknown	Substantially equivalent to the predicate devices. 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:

- 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)
- Determination of coefficient of friction of test surfaces (per ISO 7176-13)
- 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)
- EMC testing (per ISO 7176-21)
- Batteries and chargers per (per ISO 7176-25)
- Vocabulary (per ISO 7176-26)
- Changing occupant posture (per ISO 7176-30)
- Evaluation and testing within a risk management process (per ISO 10993-1)
- *In vitro* cytotoxicity (per ISO 10993-5)
- Irritation and skin sensitization (per ISO 10993-10)

The results of these tests indicate that the Magic 360 Power Wheelchair are 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 Magic 360 Power Wheelchair is assessed to be substantially equivalent to the predicate devices.