January 16, 2018

Sunrise Medical (US) LLC
Nancy Gertlar
Senior Director, Regulatory Affairs and Quality Assurance
2842 Business Park Ave
Fresno, California 93727

Re: K172384
Trade/Device Name: Quickie® Q700-UP M
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: December 8, 2017
Received: December 14, 2017

Dear Nancy Gertlar:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172384

Device Name
Quickie(R) Q700-UP M

Indications for Use *(Describe)*
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.

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

Submitted By: Nancy J Gertlar
Sunrise Medical (US) LLC
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Phone: 559-294-2395
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Contact: Nancy J Gertlar
Senior Director Regulatory Affairs and Quality Assurance
Nancy.gertlar@sunrise.com

Date Summary Prepared: **December 1, 2017**

Trade Name: **Quickie® Q700-UP M**

: **Common/**
Classification Name: **Wheelchair, Standup**
Standup wheelchair
Product Code **IPL**
21 CFR 380.3900

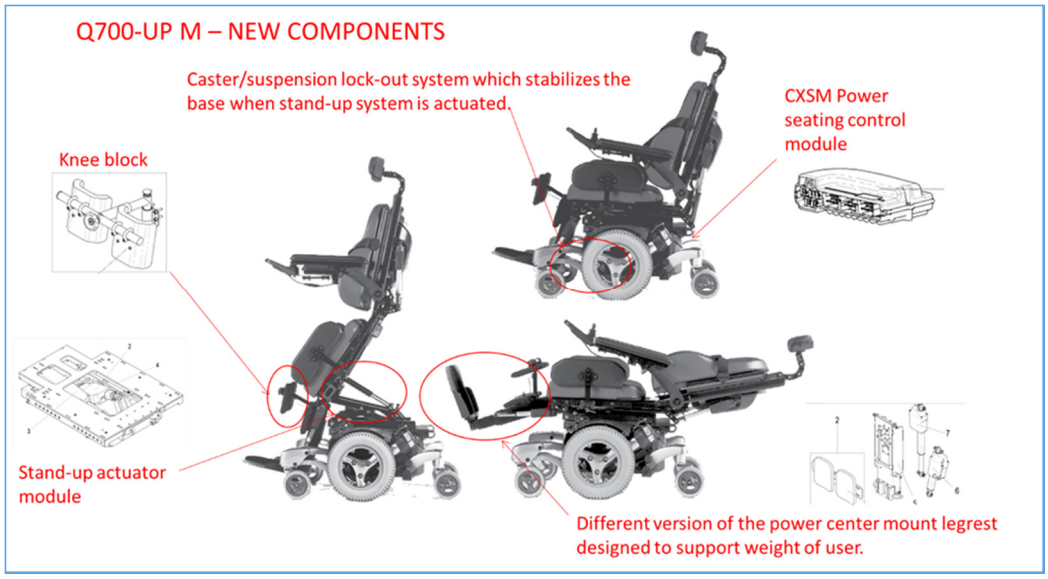
Primary Predicate Device:	Levo C3 Power Wheelchair K083017 Product Code IPL 21 CFR 890.3900
Reference Device:	Sunrise Medical Quickie® Pulse 6SC K142457 Product Code ITI 21 CFR 890.3860

Description of the Q700-UP M:

This submission covers the **Q700-UP M** which includes the following new components to the Sunrise Medical Quickie® Pulse 6SC:
(illustration follows)

1. Requires a knee block that was a previous option
2. Adds a stand-up actuator (PG Drives Technology) to power the stand-up feature
3. Requires a different version of the power center leg-rest to support the patient's weight when standing.

4. Adds a CSXM power seating control module (PG Drives Technology) to control the seating during standing
5. A caster / suspension lock-out system to stabilize the base when stand-up is actuated.



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.

Q700-UP M

The Sunrise Medical Quickie® Q700-UP M power wheelchairs provide seating and standing function for patients who cannot stand on their own. This chair is intended for patients with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, and other diseases and conditions which limit a patient's mobility.

Indications for Use

The indications for use of the Quickie® Q700-UP M are listed in the table (Table 1) below and compared to the primary predicate device, the Levo C3. The table also demonstrates that the indications for use of the Quickie® Q700-UP M are substantially equivalent to the Levo C3.

Table 1. Primary Predicate Comparison of Indications For Use

Quickie® Q700-UP M	**Levo C3 (Primary Predicate)**	**Comparison**
K172384	K083017	
The Sunrise Medical Quickie® Q700-UP M power wheelchairs are battery operated devices,	The LEVO C3 power wheelchair with optional seating and	Equivalent

that are indicated for medical purposes to provide mobility and repositioning of the user, including a stand-up feature.	standing position function may be of interest for any individuals who needs a power wheelchair and cannot stand up on their own such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc..	

Principles of Operation

Sunrise Medical power wheelchairs use components typically found on most wheelchairs, including but not limited to rigid seat frame, backrest, push handles, armrests, cushion, footrests and casters. The wheelchair can be customized with various optional add-ons. Accessories that may be added after-market include items such as positioning belts, backpacks, seat pouches, oxygen tank holders and IV poles. The Sunrise Medical power wheelchairs are center-wheel-drive power wheelchairs which will perform optimally on firm even surfaces such as concrete, asphalt and indoor flooring.

The braking system can be initiated by either automatic or electric means. The brakes are automatically on except when the wheelchair is turned on and the joystick has been moved away from the neutral position. When the joystick is released or moved back to neutral, the brakes engage again. If the electrical brake system fails, the brakes will default to the closed, or "brakes on" position, thereby stopping the wheelchair.
A control system (i.e., controller and joystick) controls motor, brakes, drive wheel and batteries. This product is appropriate for use by any individual who can drive a power wheelchair without having to utilize the services of an attendant. In addition, the controls give the optional capability for attendant control. The controller is fully programmable.

The new feature for this model, the Quickie® Q700-UP M, is the ability for the patient to stand up, completely or partially, to facilitate reaching, working eye to eye with colleagues and provide more comfortable resting positions.

The actuator added for this feature articulates the chair (under the joystick's control) and seating to allow the patient position to come to a standing position if desired. The seating, straps, knee brace and leg rests stabilize the patient so they do not slip down and slump during the stand-sit or sit-stand operation.

Predicate Comparison of Major Technical Features

The following tables provides a comparison of the primary predicate device (Levo C3 – Table 2) and the reference device (Quickie Pulse 6SC - Table 3) with the QM700-UP M to demonstrate substantial equivalence.

Table 2. Predicate Comparison with the Primary Predicate

Feature	**Primary Predicate: Levo C3 Power Wheelchair**	**Q700-UP M Power Wheelchair**	**Comparison**
510(k) Number	K083017	K172384	
Product Code	IPL 890.3900	IPL 890.3900	Identical
Device Description	The LEVO C3 with optional seating and standing position function is center wheel driven, battery powered, motor driven power wheelchair and is controlled by the PG Drives Technology's power wheelchair controller "VR2". The joystick is integrated in the controller. The wheelchair is powered by two 12V/55Ah or two 12V/72Ah batteries with a theoretical driving range of 25km (55Ah), 35km (72Ah). The LEVO C3 power wheelchair is a product which changes people's position in/from seating or/to standing but	Q700-UP M powered wheelchairs: • Are center-wheel-drive power wheelchairs • Perform optimally on firm even surfaces such as concrete, asphalt and indoor flooring • Designed to: - Overcome a maximum obstacle height of 2.5" (not in standing mode) - Operate at a maximum incline angle for safe operation of 10° (not in standing mode) - Travel a maximum distance of 21 miles on fully charged battery - Work indoors and out at care facilities and private residences	Equivalent

	also any position in between. The electrical positioning change is integrated in an electrical center wheel drive power wheelchair that performs high indoor and outdoor mobility in any optional possible position. For security, the speed is reduced to half speed as soon as the patient is not	- The wheelchair is powered by 2 12V Group 24 or Group 34 batteries - It is controlled by PG Drives Technology's power wheelchair controller "R-Net" and has a slow "Creep Mode" speed when in the	
Picture (in standing mode)			Equivalent
Seat width	12.6 - 20.5 inches	16 – 22"	Equivalent
Total width	24.8 inches	25"	Equivalent
Total length	41.3 inches	36"	Functionally Equivalent
Seat plate depth	13.8–24.8 inches	16 – 22"	Functionally Equivalent
Armrest height	5.9–14.1 inches	6.3"-12"	Functionally Equivalent
Turning circle	43 inches	43 inches	Identical
Speed	3.7/ 5 /6.2 mph options	6 or 8 mph options	Functionally Equivalent
Range (with 55 Ahr Batteries)	15.5 miles	21 miles	Functionally Equivalent
Manageable gradient	15° (33%) actually 28%	10° (18%)	Functionally Equivalent
Max. curb height	4 inches	4 inches	Identical
Max. chair weight	407 lbs.	375 lbs.	Equivalent
Max. user weight	310 lbs.	265 lbs.	Reduced weight capacity
Transport volume max.	37.8 x 24.8 x 27.1 inches	41 "x 25"x 29"	Functionally Equivalent

Controller(s)	PGDT VR-2 Controller Std. PGDT R-Net Controller Optional	PGDT R-Net Controller Std.	Equivalent
Joystick Mounting	Standard Swing-away Retractable	Standard Swing-away Retractable	Equivalent
Attendant Controls	Optional, for VR-2 or R-Net	Optional, for R-Net	Equivalent
Batteries	Group 22Sealed lead – 48 AH Group 24Sealed Gel – 73 AH	Group 24 – 73Ahr Group 34 -50 Ahr	Equivalent
Power stand-up feature	Requires chest support and knee support options	Chest support and knee support standard	Identical
Light kit option:	Front & Rear with Turn Signal	Front & Rear with Turn Signal	Identical

Table 3. Comparison with the Reference Device

Feature	**Reference Device: Quickie Pulse 6SC**	**Q700-UP M Power Wheelchair**	**Comparison**
510(k) Number	K 142457	K 172384	
Product Code	ITI 890.3860	IPL 890.3900	Additional stand-up feature
GENERAL			
User Weight (Max)	300 lb.	265 lb.	Equivalent (limited by standup feature)
Structural Materials	Steel and aluminum frame structure which is welded and powder coated and utilizes standard foams and covers for the seat.	Steel and aluminum frame structure which is welded and powder coated and utilizes standard foams and covers for the seat.	Identical
Biocompatibility	Uses materials common to many Wheelchairs.	Uses materials common to many Wheelchairs.	Identical

Maximum speed	6.0 mph for Quickie® Pulse 6SC power wheelchairs	6.0 mph, with 8.0 mph option	Equivalent
BASE			
Overall dimensions (width x length)	24” x 34”	25” x 36”	Equivalent
Maximum total weight of base	130 lbs.	152 lbs.	Equivalent
Batteries	22NF, 52 Ahr sealed lead acid or gel cell batteries	24V (2x12V) / 73 Ah/20h. Maintenance free or 24V (2x12V) / 60 Ah/20h. Maintenance free	Equivalent
Drive wheels	13” diameter	14” diameter	Equivalent
Caster wheels	7” front, 6” rear	6” Front & Rear	Equivalent
Motors/gearbox	DC Permanent Magnet motor with gearbox Output speed: 163rpm Gear ratio: 26:1 Peak power: 910 W @ 90A	6.0 Motor Package Output Speed: 163 rpm Gear Ratio: 26:1 Peak Power:1026W @120A 8.0 mph Motor Package: Output speed: 220 rpm Gear Ratio: 26:1 Peak Power: 1293W @120A	Equivalent
Anti-pitch mechanism for climbing	Additional anti-pitch lock-out.	Additional anti-pitch lock-out.	Equivalent
Cosmetic	Product is made from a steel tubular box frame, with cast aluminum front and rear caster arms and shrouded with ABS plastic covers.	Product is made from a steel tubular box frame, with cast aluminum front and rear caster arms and shrouded with ABS plastic covers.	Equivalent

Picture			Equivalent
SEAT			
Seat options	Standard rehab seat (accommodates after-market seating). Captain's seat. Comes with cushions and upholstery.	SEDEO UP Recline (required by stand-up feature)	Equivalent
Minimum seat height	16.2"	16.2"	Identical
Lift, tilt, recline range	Lift range 0-12" Tilt range 0-50º Recline range 0-172º	Lift range 0-12" Tilt range 0-50º Recline range 0-172º	Identical
Lift, tilt, recline capacity	Lift capacity 300 lbs. Tilt capacity 300 lbs. Recline capacity 250 lbs.	Lift capacity 265 lbs. Tilt capacity 265 lbs. Recline capacity 265 lbs.	Equivalent (limited by stand-up feature)
Seat dimensions	Width 12-24" Depth 12-22"	Width 16 - 22" Depth 16 - 22"	Equivalent
CONTROLLER			
Controller type	VR2 from PGDT (standard) R-Net from PGDT (optional)	R-Net from PGDT	Equivalent (limited by stand-up feature)
Supply voltage	24 V dc	24 V dc	Identical
Operating voltage	35 V dc	35 V dc	Identical
Reverse battery voltage	-40 V dc	-40 V dc	Identical
PWM frequency	19.5 kHz ± 1%	19.5 kHz ± 1%	Identical
Brake voltage	Harness with in-line connector	Harness with in-line connector	Identical
Brake current	Minimum 100 mA Maximum 1 A	Minimum 100 mA Maximum 1 A	Identical
Charging current	12 A rms max	12 A rms max	Identical

Charger connection	Only Neutrik NC3MX	Only Neutrik NC3MX	Identical
Actuator current	Maximum 10 A	Maximum 10 A	Identical
Maximum drive current	VR290: 90A R-Net EL 90: 90A	RNet 120A Controller	Equivalent with additional max current output.
Moisture resistance	Compliant with ANSI RESNA WC-9	Compliant with ANSI RESNA WC-9	Identical
Operating temperature	-25ºC to 50ºC	-25ºC to 50ºC	Identical
Storage temperature	-40ºC to 70ºC	-40ºC to 70ºC	Identical
Joystick Mount	Fixed mount (standard) Height adjustable (standard) Swing-away (option)	Fixed mount (standard) Height adjustable (standard) Swing-away (option)	Identical
Controller Connector	Harness with in-line connector	Harness with in-line connector	Identical
USER INPUT CONTROLS			
Number of drive profiles	5	5	Identical
User input	Joystick and hand control buttons	Joystick and hand control buttons	Identical
On/off button	Yes	Yes	Identical
Speed up / speed down buttons	Yes	Yes	Identical
Horn button	Yes	Yes	Identical
Actuator control	Versions available with and without actuator control buttons	Versions available with and without actuator control buttons	Identical
Number of actuators for lift, tilt, recline	2	6 - tilt, stand-up, recline (2), power legrests (2), lift.	Equivalent
Battery state indicator	LEDs	LEDs	Identical
Electronics package	Electronics in both hand control module and motor control module	Electronics in both hand control module and motor control module	Identical

Programming tool	Hand held programmer	Hand held programmer	Identical
External drive inhibit input	Yes	Yes	Identical
Attendant control	Option with R-Net system	Option with R-Net system	Identical
Bluetooth PC mouse replacement	Option with R-Net system	Option with R-Net system	Identical

Use of Standards

The table below (Table 4) provides a summary of all the various standards to which the Q700-UP M conforms.

Table 4. List of recognized standards to which the Q700-UP M Complies

Recognized Standard	**Outcome**
ISO 7176-1 [ANSI/RESNA WC-1/1]: Determination of Static Stability	Pass
ISO 7176-2 [ANSI/RESNA WC-2/2]: Determination of Dynamic Stability of Electrically Powered Wheelchairs	Pass
ISO 7176-3 [ANSI/RESNA WC-2/3]: Determination of effectiveness of brakes	Pass
ISO 7176-4 [ANSI/RESNA WC-2/4]: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance	Pass
ISO 7176-5 [ANSI/RESNA WC-1/5]: Determination of dimensions, mass and maneuvering space	Pass
ISO 7176-6 [ANSI/RESNA WC-2/6]: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs	Pass
ISO 7176-7 [ANSI/RESNA WC-1/7]: Method of measurement of seating and wheel dimensions	Pass
ISO 7176-8 [ANSI/RESNA WC-1/8]: Requirements and test methods for static, impact and fatigue strengths	Pass
ISO 7176-9 [ANSI/RESNA WC-2/9]: Climatic tests for electrically powered wheelchairs	Pass
ISO 7176-10 [ANSI/RESNA WC-2/10]: Determination of obstacle-climbing ability of electrically powered wheelchairs	Pass
ISO 7176-14 [ANSI/RESNA WC-2/14]: Power and control systems for electrically powered wheelchairs - Requirements and test methods	Pass
ISO 7176-15 [ANSI/RESNA WC-1/15]: Requirements for information disclosure, documentation and labeling	Pass
ISO 7176-16 [ANSI/RESNA WC-1/16]: Resistance to ignition of upholstered parts - Requirements and test methods	Pass

ISO 7176-19 [ANSI/RESNA WC-4/19]: Wheeled mobility devices for use as seats in motor vehicles	Pass
ISO 7176-21 [ANSI/RESNA WC-2/21]: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters	Pass
ISO 10993-5: Biological evaluation of medical devices	Pass
ISO 7176-25: Batteries and chargers for powered wheelchairs and motorized scooters - Requirements and test methods	Pass
RESNA WC-1:2009 Section 20: Determination of the Performance of Stand-up Type Wheelchairs	Pass

Clinical Testing and/or Non-Clinical Testing

No Clinical Testing is required for this submission

Conclusion

All verification and validation testing conducted demonstrate that the Quickie® Q700-UP M is substantially equivalent to the primary predicate device:

Primary Predicate Device:	Levo C3 Power Wheelchair K083017 Product Code IPL 21 CFR 890.3900
Reference Device:	Sunrise Medical Quickie® Pulse 6SC K142457 Product Code ITI 21 CFR 890.3860