DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 14, 2016

Sunrise Medical (US) LLC
Laurie Roberts
Director, Regulatory Affairs
2842 Business Park Av
Fresno, California 93727

Re: K160031
Trade/Device Name: Quickie Pulse (Models 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC) and Zippie ZM-310 (Models BC, SC)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 9, 2016
Received: June 9, 2016

Dear Laurie Roberts:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160031

Device Name
Quickie Pulse (Models 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC) and Zippie ZM-310 (Models BC, SC)

Indications for Use *(Describe)*
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.

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.

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

Submitter

Company Sunrise Medical (US) LLC
2842 Business Park Avenue
Fresno, CA 93727

Tel: 800-333-4000
Fax: 559-294-2872

Contact Laurie Roberts, MS, RAC
Director, Regulatory Affairs

Device

Trade name Quickie Pulse (Models 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC) and Zippie ZM-310 (Models BC, SC)

Class name Wheelchair, powered (21 CFR 890.3860)

Product code ITI

Class 2

Predicate

Devices Quickie Pulse: Models 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC and Zippie ZM-310: Models BC & SC; legally marketed per 510(k): K142457

Recalls These predicate devices have not been subject to a design-related recall.

Device Description

Overview Quickie and Zippie wheelchairs are battery-powered, user-controlled, electric wheelchairs. All models of these wheelchairs will be offered with an optional wireless pointer control feature.

Wireless pointer control feature This option entails adding a Bluetooth Mouse Module (BMM)—a small Bluetooth transmitter—mounted to the chair and wired into its control bus.

With BMM in place, the wheelchair's controller can then use the pointer-control feature built into the BMM hardware and software.

Pointer control can only be activated when the wheelchair is stationary and not actively performing wheelchair functions.

Continued on next page

Device Description (continued)

Purpose of feature	The BMM lets users use the chair's joystick, or other input device, to control the pointer functions of Bluetooth-enabled devices (such as personal or tablet computers) while the chair is not in operation.
Model distinctions	The wireless pointer control feature will be offered on all models of the Quickie Pulse and Zippie ZM-310 series chairs. Technologically, all of these chair designs are identical. Model designations relate to widths and heights of their seats and various components: such as seating, wheels, and other options available. • Quickie Pulse chairs are sized to fit medium to large size individuals • Zippie ZM-310 chairs fit individuals of smaller stature—including children
Use environment	These chairs, along with the BMM, are meant for use in healthcare facilities, in the home, outdoors, and other places of individual activity for the disabled.

Intended Use

Indications for Use	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.
Feature fact	The Indications for Use for the Quickie and Zippie power wheelchairs with the wireless pointer control are identical to those for the chairs that do not have the feature. The feature is strictly an add-on for the convenience of the users.

Technological Characteristics and Comparison

Design	Technological characteristics—design, materials, motors, electronics, power source, etc.—are identical to the predicate devices with the exception of the addition of the BMM.
BMM option	By adding the BMM, wireless pointer control can be engaged. The BMM adds • The ability to use the chair's joystick, or other input device, to control the pointer functions of Bluetooth-enabled electronic devices • Some extra wiring to the electronic system raising the issue of continued electromagnetic compatibility for the chairs • A low-power radio-frequency transmitter in the 2 to 2.5 GHz Bluetooth frequency range raising the issue of electromagnetic emissions interfering with chair brake function (chair is not in motion at the time of transmission but may be braking to hold chair on an incline)

Technological Characteristics and Comparison (continued)

Parameters	**K160031 (subject device)**	**K142457 (predicate device)**
Models	Quickie Pulse® (Models: 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC) and Zippie® ZM-310 (Models: BC & SC)	Same
Intended Use	To provide mobility to persons limited to a seating position that have the capability of operating a powered wheelchair	Same
Indications for Use	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.	Same
Bluetooth feature available	YES Bluetooth technology operates in unlicensed industrial, scientific and medical (ISM) band at 2.4 to 2.485 GHz, using a spread-spectrum, frequency-hopping, full-duplex signal at a nominal rate of 1600 hops/sec. Class 1 output – used primarily in industrial use cases – 100 meters Power is 100mW max for Class 1	NO
Other technical features	Same	Same
Evaluation methods	Same	Same

Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Performance	Operational performance of wireless pointer function without detriment to wheelchair function or features • Chair's electrical braking continued to hold on a maximum slope during BMM operation • Wireless pointer function properly executed on typical external Bluetooth-enabled electronic device from wheelchair inputs
EMC	Electromagnetic compatibility testing carried out to cover functional verification and device performance to ANSI/RESNA WC2 testing plus over extended frequency range through 3.0 GHz with BMM mounted in its closest proximity (worst-case) position to the wheelchair controller demonstrated • Immunity of total chair system with BMM mounted and connected • No effect on chair during BMM activation
Software qualification	Wireless pointer function demonstrated while chair not in operation, qualifying the BMM and its software by successful device performance.

No animal or clinical data necessary to demonstrate the performance of this option.

Conclusion

The performance data support the electromagnetic compatibility of the BMM to the Quickie and Zippie power wheelchairs and their operation. The operational verification and validation of the wireless pointer control feature demonstrate that the feature performs as intended in the specified use conditions. Thus, the optional feature added to these chairs produce comparable results to the predicate devices for the same intended use. The devices are substantially equivalent to their predicates.