DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 18, 2014

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

Re: K142457
Trade/Device Name: Quickie® Plus Powered Wheelchairs: 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC and Zippie® Powered Wheelchairs: ZM-310 BC & ZM-310 SC
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: November 12, 2014
Received: November 17, 2014

Dear Ms. 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" (21CFR 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,

Felipe Aguel -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142457

Device Name
Quickie® Plus Powered Wheelchairs: 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC
Zippie® Powered Wheelchairs: ZM-310 BC & ZM-310 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.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

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

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

Contact Person: Laurie Roberts, MS, RAC
Date Prepared: August 29, 2014

II. DEVICE

Name of Devices: Quickie® Pulse 6BC, 6SC, 6CC, 5BC, 5CC, 6MPC
Zippie® ZM-310 BC & ZM-310 SC
Common or Usual Name: powered wheelchair
Classification Name: Wheelchair, Powered (21 CFR 890.3860)
Regulatory Class: II
Product Code: ITI

III. PREDICATE DEVICE

Quickie Rhapsody, MWD Series II Power Wheelchair, K062701 (Primary Predicate)
Quickie Rhythm Power Wheelchair (Controller Change), K083249 (Secondary Predicate)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Quickie® and Zippie® power wheelchairs are designed for indoor and outdoor use at care facilities and private residences. The pediatric variant of the Quickie® Pulse 6, branded the Zippie® ZM-310, is intended to provide a slightly broader range of seating size options for people that are smaller in stature—including children. It varies from the Quickie® Pulse 6 only in having smaller seat options.

V. 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.

The wording of the Indications for Use statement has been modified to align it more closely with the wording of 21 CFR 890.3860 (Powered Wheelchair) but the intent is the same as for the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The Quickie® and Zippie® power wheelchairs are center-wheel-drive battery-powered wheelchairs which will perform optimally on firm even surfaces such as concrete, asphalt and indoor flooring.

The wheelchairs have steel and aluminum frame structure which is welded and powder coated and utilizes standard foams and covers for the seat.

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.

Actuators allow the seating to be adjusted to suit the user and activity.

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 has the ability to 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 optional drive controller R-net system provides further features. The controller is fully programmable.

Technological characteristics are the same as for the predicate devices.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The materials used for the Quickie® and Zippie® power wheelchair components which have patient contact are the same as those used in the primary predicate device. Therefore, further testing was not required.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and electromagnetic compatibility testing of Quickie® and Zippie® power wheelchairs was carried out to cover functional verification and device performance. Testing established correct functionality of the wheelchairs according to the relevant ANSI/RESNA Wheelchair standards.

Software Verification and Validation Testing

The Quickie® and Zippie® power wheelchairs contain software within the drive control units. The software in the two products is identical. A Letter of Authorization was provided by the supplier of the drive controller units in order access the medical device Master File for the controllers.

Mechanical and acoustic Testing

Mechanical testing of Quickie® and Zippie® power wheelchairs was carried out to cover functional

verification and device performance. Testing established correct functionality of the wheelchairs according to the relevant ANSI/RESNA Wheelchair standards. No acoustic testing was required to demonstrate device safety and effectiveness of the wheelchair.

Animal Study

Animal performance testing was not required to demonstrate device safety and effectiveness of the wheelchair.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the wheelchair.

VIII. CONCLUSIONS

Testing carried out for the Quickie® and Zippie® power wheelchairs indicates that they meet design and performance functional requirements and function equivalently to the predicate devices. The devices meet the relevant ANSI/RESNA Wheelchair standards.

This information indicates that the Quickie® and Zippie® power wheelchairs are equivalent to the predicate devices in terms of device safety and effectiveness.