FEB 1 1 2005

K043435

Section 1.0 510(k) Summary

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:		Sunrise Mobility Products Division 2842 Business Park Avenue Fresno, California 93727-1328
FDA registration number of the manufacturer of the new device:		2082643
Official contact person for all correspondence:		Joseph E. Olsavsky Director – Regulatory Affairs Sunrise Medical 100 DeVilbiss Drive Somerset, PA 15501 Phone: 814-443-7690 Fax: 814-443-7597 Cell: 814-521-9152 Email: joe.olsavsky@sunmed.com
Date Prepared:		November 18, 2004
Device Name:		Quickie Model Powered Wheelchair
Proprietary name of new device:		Quickie Interchange FWD w/ Lift
Generic name of the device:		Quickie Powered Wheelchair
Classification of the predicate device:		Class II
Classification of new device:		Class II
Classification Panel:		Physical Medicine
Panel Code:		ITI
CFR Regulation Number:		21 CFR 890.3860
Predicate Device Name(s) and 510(k) number(s):		*Arrow FWD Power Wheelchair* **(K991168)**

Description of Device:

The Quickie Interchange FWD w/ Lift Power Wheelchair is a High End/Mid-Range Rehabilitation type Power Chair Base design that offers the functionality to be used as a Front Wheel drive or a Rear Wheel drive base without changing major frame parts. The system allows for reassembling parts that will for either front or rear wheel drive function. The design will offer a modular approach within the drive base as interface to adopt various seating & wiring elements. The device utilizes components typically found on most wheelchairs, including but not limited to rigid seat frame, backrest, push handles, armrests, cushion, footrests and casters. Accessories that may be added after market include items such as positioning belts, backpacks, seat pouches, oxygen tank holders, IV poles, etc. As a motorized wheelchair, it also contains a controller, joystick, motor, brakes, drive wheel and batteries. This product is appropriate for use by any individual who has the ability to drive a powered wheelchair without having to utilize the services of an attendant. Sunrise Medical makes no claim as to the therapeutic effectiveness of the product. Sunrise Medical's only claim relates to the ability of the product to provide an optional means of mobility for physically challenged people.

Comparison of Device Technological Characteristics to Predicate Devices:

This device has similar technological characteristics as the predicate devices. They all use steel and aluminum in their frames and components, and standard foams and covers for the slings, backs and cushions. Microprocessors are typically used with a programmable controller, and the end-user controls the chair by using a joystick or other equivalent command mode. Motors use 24 volt DC rechargeable batteries for an energy source. The operating speeds, maneuverability, power modules, hand controls, seat types, drive wheels, and climbing ability are substantially equivalent and are recommended for indoor and moderate outdoor use. The standard accessories and components are common to all power wheel chair devices.

See Section 8.0.

Statement of Intended Use:

The Quickie Interchange FWD w/ Lift Power Wheelchair's intended use is to provide mobility to persons limited to a seating position, that have the capability of operating a powered wheelchair. The Quickie Interchange FWD w/ Lift Power Wheelchair provides an optional means of mobility for physically challenged people.

Non-Clinical Testing:

This device has been tested to appropriate ISO & ANSI/RESNA standards and other applicable requirements passing all test protocols.

As required by FDA's July 26, 1995, draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and

Powered Wheelchairs, and Motorized Three-Wheeled Vehicles", the Quickie Interchange FWD w/ Lift Power Wheelchair was tested in accordance with the ISO EMC Standard "ISO 7176-14:1997, Wheelchairs - Part 14: Power and Control Systems for Electric Wheelchairs - Requirements and Test Methods". The Quickie Interchange FWD w/ Lift Power Wheelchair met the required performance criteria and functioned as intended.

See Section 10 Test Reports and Attachment A.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the Sunrise Medical Quickie Interchange FWD w/ Lift Power Wheelchair to the Invacare Arrow FWD Power Wheelchair, together with the results of testing demonstrates the device to be substantially equivalent to the predicate device in terms of meeting performance criteria and functioning as intended.

Conclusion: The Sunrise Medical Quickie Interchange FWD w/ Lift Power Wheelchair is substantially equivalent to the predicate device listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Joseph E. Olsavsky
Director, Regulatory Affairs
Sunrise Medical
100 DeVilbiss Drive
Somerset, Pennslyvania 15501-2125

Re: K043435
Device Name: Quickie Interchange FWD w/Lift Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: January 28, 2005
Received: January 31, 2005

Dear Mr. Olsavsky

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division Of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K043435

Device Name: Quickie Interchange FWD w/ Lift Power Wheelchair

Indications for Use: The Quickie Interchange FWD w/ Lift Power Wheelchair's intended use is to empower physically challenged individuals by providing a means of mobility.

Prescription Use_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043435