

NOV 6 1998

K981462

13.0 510(k) SUMMARY OF SAFETY AND EFFICACY

Submitter: Sunrise Medical – Mobility Products Division
7477 East Dry Creek Parkway
Longmont, CO 80503
Phone (303) 218-4595 Fax (209) 218-4565
Rebecca Andersen

Date: November 5, 1998

Name(s) of the device(s): S-525 Power Wheelchair

Identification of predicate device(s):

- 1) Quickie P190 by Sunrise Medical
- 2) Quickie P120 by Sunrise Medical
- 3) Sabre by Everest & Jennings
- 4) Ranger II by Invacare Corporation

Description of the device:

The Quickie P190 R (or S525) is a medium duty, conventional, rear wheel drive, and rigid frame power wheelchair.

The Quickie P190R Power Wheelchair consists of typical components found on most wheelchairs, such as push handles, armrests, backrest, seat frame, cushion, footrest 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, a joystick, a motor, brakes, a drive wheel and 2 batteries.

Like most power wheelchairs, the joystick is the user interface. It transfers the rider's intentions to command the chair. When the control is activated, or moved out of the center position, the motor brake is energized and released, allowing the chair to move in the direction of the activation. When the activation device (joystick or alternate input device) is released, the chair slows to a stop and the motor brake is automatically re-engaged. These dynamic "on command" brakes allow the user to stop by letting go of the activation device.

If the chair loses power, the motor brake is automatically engaged and the chair comes to a stop. To prevent the rider from becoming stranded, the chair may be pushed. The chair incorporates a "free wheel" device motor lock disengagement option. This option allows the drive train to be manually disengaged, enabling the chair to be more easily pushed by an assistant. It should be noted that the chair would not have electronic brakes when in the "free wheel" mode. However, the manual wheel locks (also optional) will still function if engaged.

Intended use:

Sunrise powered wheelchairs empower physically challenged persons by providing a means of mobility.

Comparison of device characteristics to predicate(s):

This device has similar technological characteristics as the predicated devices. They all use steel and aluminum in their frame and components, and standard foams and covers for the slings and backs. Microprocessors are typically used with a programmable controller, and the rider controls the chair using a joystick or other equivalent command mode. Motors use permanent magnets, employing 24 volt D.C., with rechargeable deep cycle batteries for an energy source. The operating speeds and maneuverability are substantially equivalent, and recommended for indoor or moderate outdoor use. The standard accessories and components are common to all power wheel chair lines.

Testing:

This device has been tested to both ISO7176 and ANSI/RESNA Wheelchair Standards. They include:

- Static Stability
- Dynamic Stability
- Effectiveness of Brakes
- Energy consumption
- Overall Dimensions
- Maximum Speed acceleration and retardation
- Static Impact
- Fatigue Strength
- Climatic Test
- Obstacle Climbing Ability
- Testing of Power and Control System
- EMC Testing

We have also tested to the Proposed:

Addition to ANSI/RESNA W/C 14 Electromagnetic Compatibility Requirements for Powered Wheelchairs and Motorized Scooters Version 1.5 Dated 1/11/94

ISO EMC Draft Standard 7176-14 Rifled Draft ISO EMC Group Proposal Electromagnetic Compatibility Addition Dated 4/3/95 Regarding Electromagnetic Compatibility Requirements for Powered Wheelchairs and Motorized Scooters.

Safety:

An analysis of complaints against Sunrise power chairs was completed and charted. This analysis was supported by a literature search, which was conducted by a third party to determine the number of complaints, MDR's and recalls that have been reported to the FDA concerning wheelchairs in general. This information was summarized, and presented in a Management Review report dated 2/20/97. Subsequent complaints against Sunrise are presented in a chart entitled "Total Sunrise Medical Power Product Complaints". The data and charts are included as Attachment 13 - A. The analysis demonstrated common issues across all manufacturer product lines, and varying levels approximately comparable to relative market share. Sunrise has concluded that there are no use issues exclusive to Sunrise chairs at this time.

Efficacy

Articles are being provided on the use and efficacy of power wheelchairs.

- 1) "Power Wheelchair Comparison", Ian Denison, 14th International Seating Symposium Proceedings, pp. 113 – 116, February 1998.
- 2) "Front, Back or in the Middle: Understanding Mid-Wheel Drive", Mark Greig, Sunrise Horizons, Vol 1, Number 4, pp. 6 – 7, February 1998.
- 3) "Dynamic Wheelchair Stability: Reliability of an Ordinal Scale", R. L. Kirby, D. A. MacLeod, R. E. Duggan, et. al., Proceedings of RESNA '97, pp. 237 – 239.
- 4) "When Wheelchairs Tip backwards Beyond Their Stability Limits", R. L. Kirby, M. DiPersio, and D. A. MacLeod, Proceedings of RESNA '96, pp. 180 – 182.
- 5) "Effect on Wheelchair Stability and Maneuverability of Varying the Position of the rear Antitip Device: A Theoretical Model", R. L. Kirby, A. V. Thoren, B. D. Ashton, and S. A. Ackroyd-Stolarz, Proceedings of RESNA '93, pp. 313 – 315.

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Conclusion:

The Quickie S-525 (a.k.a. P190R) Power Wheelchair is substantially equivalent to the predicated devices listed in this 510(k); the technology and construction of the S - 525 does not raise any new issues of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Rebecca Andersen
Vice President, Quality and Regulatory Affairs
Sunrise Medical, Inc.
Mobility Products Division
7477A East Dry Creek Parkway
Longmont, Colorado 80503

Re: K981462
Trade Name: S-525 Power Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: August 7, 1998
Received: August 10, 1998

Dear Ms. Andersen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

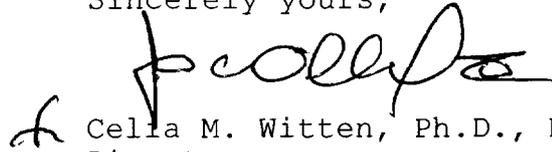
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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

Enclosure

Indications for Use

Sunrise powered wheelchairs empower physically challenged persons by providing a means of mobility.

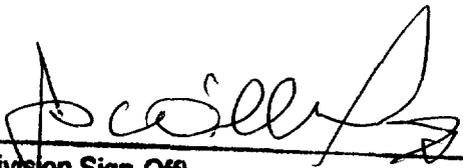
510(k) number: K981462

Device name: S-525

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR801.109)

Over-the-counter use



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981462