

NOV 6 1998

K 983677

13.0 510(k) SUMMARY OF SAFETY AND EFFICACY

Submitter: Sunrise Medical (303) 218-4500
Mobility Products Division
7477 East Dry Creek Parkway
Longmont, CO 80503

Rebecca Andersen
Date: October 13, 1998

Name(s) of the device(s): G-424 Power wheelchair
Identification of predicate device(s): Modification to a Sunrise Device
1) Quickie P200 by Sunrise Medical
2) Quickie P120 by Sunrise Medical

Description of the device:
The G-424 is a mid-wheel drive, moderate duty chair that comes in one basic configuration. It is available with the Pilot controller.

The Quickie G-424 Power Wheelchair consists of the same basic components found on the P200, such as a frame with suspension, seat, armrests, footrest, cushion, casters and drive wheels. Accessories include items such as positioning belts, backpacks, seat pouches, oxygen tank holders, IV poles, etc. As motorized wheelchairs, they also contain controllers, joysticks, motors, brakes, drive wheels and batteries

Key changes between the P200 and the G-424 are the replacement of anti-tip wheels with anti-tip casters, change from aluminum to steel frame construction, revised suspension, revised modular seat and use of the Pilot controller from Penny & Giles. ". Aesthetics have been improved by adding a plastic thermoformed molded cover.

Intended use:
Quickie powered wheelchairs empower physically challenged persons by providing a means of mobility. This includes conditions in all ages such as :
Arthritis Tetraplegic Multiple Sclerosis
Amputee Quadriplegic Polio
Paraplegic Spina Bifida Geriatric conditions
Cerebral Palsy Head Injury or Trauma And other immobilizing or debilitating conditions
Hemiplegic Muscular Dystrophy

Comparison of device characteristics to predicate(s):
The proposed device modifications combine technological characteristics from two Sunrise predicate devices.

Key changes between the P200 and the G-424 are the replacement of anti-tip wheels with anti-tip casters, change from aluminum to steel frame construction, revised suspension, revised modular seat and use of the Pilot controller from Penny & Giles. ". Aesthetics have been improved by adding plastic thermoformed molding covers.

Testing:

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

They include:

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

Safety:

The Quickie G-424 Power Wheelchair is substantially equivalent to the existing Sunrise Medical predicate devices. The modifications to this device have been validated using appropriate Design Controls and therefore have been demonstrated to be “non significant” with respect to safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 6 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983677
Trade Name: G-424 Power Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: October 13, 1998
Received: October 19, 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.

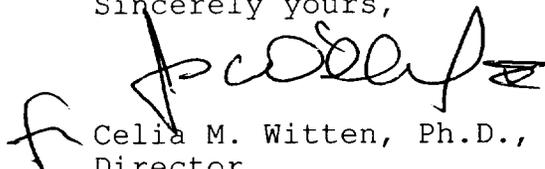
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

