

K982989

**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

Date: Rebecca Andersen  
 August 25, 1998

Name(s) of the device(s):

Suspension Wheelchair Series

Identification of predicate device(s):

- 1) Quickie GPS by Sunrise Medical
- 2) Action A4 by Invacare Corporation
- 3) Barracuda by Everest & Jennings
- 4) Boing by Colours

Description of the device:

Sunrise Medical Suspension Wheelchairs consists of typical components found on most wheelchairs, such as push handles, armrests, backrest, seat frame, cushion, footrest and casters. Many of these components are available in a range of sizes, shapes, angles, forms, materials or coverings. These variations allow the chairs to be configured to meet the specific desires and needs of the user. Refer to section 7 for a component diagram of a Suspension chair (figure 1); for nominal dimensions see figure 2.

Intended use:

Sunrise mechanical 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 immobiliz-
Hemiplegic	Muscular Dystrophy	ing or debilitating
		condition

Comparison of device characteristics to predicate(s):

The Suspension Wheelchair is a light weight manual chair which is intended to provide mobility based on an individual users' needs and capabilities. It is available in a range of sizes (dimensions) to allow fit to a particular user. The key change covered by this submission is the suspension feature, which allows the user to traverse uneven terrain or obstacles with greater comfort.

Testing:

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

Static Stability  
Overall Dimensions  
Fatigue Strength

Safety:

An analysis of complaints against Sunrise manual chairs was completed and charted for the period from 4/1/97 through 2/28/98. 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. The data and charts are included as Appendix C. The analysis demonstrated common issues across all manufacturers 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 manual wheelchairs.

- 1) "Mobility Technology", by Chris Bale, Home Health Products, January 1996
- 2) "Decisions, Decisions", by Marty Ball, Sports and Spokes, March/April 1997, Vol. 23, No. 2
- 3) "Rolling Revolution", by Arnold Henderson, the Wall Street Journal, September 28, 1995
- 4) "Performance Pointers", by Marty Ball, Sports and Spokes, July/August 1993, Vol. 19, No. 2

- 5) "Technology Solutions", by Mia Moody, Home Health Products, October 1996
- 6) "On the Move", by Andrea Vander Pluym, Home Care, April 1997
- 7) "Chairs, Chairs, Everywhere!", Sports and Spokes, March/April 1994, Vol. 9, No. 6 (author unidentified)
- 8) "Lightweight Chairs", HomeCare Forecast '97, Winter 1997 (author unidentified)

510(k) number:

Not assigned at the writing of this summary

Conclusion:

The Sunrise Medical Suspension Wheelchair Series is substantially equivalent to the predicated devices listed in this 510(k) ;the technology and construction of the Suspension Wheelchair Series does not raise any new issues of safety and effectiveness.



OCT 5 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K982989  
Trade Name: Suspension Wheelchair Series  
Regulatory Class: I  
Product Code: IOR  
Dated: August 25, 1998  
Received: August 26, 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.

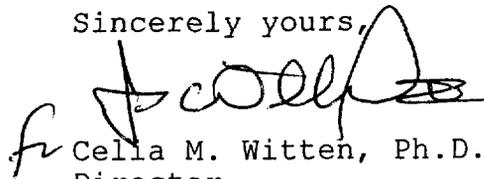
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 mechanical wheelchairs empower physically challenged persons by providing a means of mobility.

Intended use:

Quickie manual wheelchairs empower physically challenged persons by providing a means of mobility. This includes temporary and permanent 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               |
|                |                       | immobilizeing or        |
| Hemiplegic     | Muscular Dystrophy    | debilitating conditions |

510(k) number: Not assigned as of this time

Device name: Suspension Wheelchair Series

Concurrence of CDRH, Office of Device Evaluation (ODE)

# Prescription use (per 21 CFR801.109)

# **Over-the-counter use**   X  

  
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 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number   K982909