

K973673  
Nov. 20, 1997**13.0 510(k) SUMMARY OF SAFETY AND EFFICACY**

Submitter: Rebecca Andersen  
Date: September 16, 1997

**Name(s) of the device(s):**

Multiple

**Identification of predicate device(s):**

Sunrise Medical's Zippie, Quickie, and Breezy Series Wheelchairs

**Description of the device:**

For people with disabilities who are unable to transfer from their wheelchairs when traveling in motor vehicles, the wheelchair must serve as the vehicle seat. Therefore, the wheelchair must be secured to the vehicle so that it does not impose forces on its occupant and/or become a hazard to other vehicle occupants in a collision or sudden vehicle maneuver. Providing occupant protection for the wheelchair-seated occupant, therefore, requires that equipment be installed to secure the wheelchair and restrain the user.

The bus transport models of the Zippie, Quickie, and Breezy Series manual wheelchairs are chairs that can be used in motor vehicle transport. The key change covered by this submission is the addition of securement hardware to the wheelchairs so that they can be used in motor vehicle transport. Each bus transport model includes securement hardware that is bolted to the wheelchair or installed at the factory. The securement hardware is identified by proper labeling. The labeling identifies the locations to which the wheelchair tiedown and occupant restraint systems or WTORS secure to the vehicle.

WTORS are complete restraint systems for wheelchair-seated occupants. They are comprised of a system or device for wheelchair tiedown as well as a separate system for restraining the occupant. WTORS include all anchorage hardware and anchorage fasteners (or specifications for anchorage fasteners) required for installing and using the system in a vehicle. These WTORS secure the wheelchair and the occupant to the vehicle; they do not secure the occupant to the chair. WTORS will not be supplied by Sunrise Medical.

The SAE J2249 Recommended Practice (Issued October 1996), "Wheelchair Tiedown and Occupant Restraint Systems for Use in Motor Vehicles", applies to WTORS comprised of a system or device for wheelchair tiedown and a system or device for restraining the wheelchair-seated occupant. It specifies design requirements, test methods, and performance requirements for WTORS, requirements for manufacturer's instructions to installers and users, and requirements for product marking and labeling. SAE J2249 places particular emphasis on the design requirements, test procedures, and performance requirements for the dynamic performance of WTORS in a 48-km/h, 20-g frontal impact.

Sunrise chairs are configured to customer orders when sold. Configuration to order allows flexibility. Features such as width, depth, and back height are specified and may range from 14 to 22 inches. Specific configuration includes chair accessories and desired safety features. Any combination of features from the approved matrix may be configured to create the chair features needed by a given rider. It is the rider and the health care professional that determine the appropriate configuration for the user's needs. As the individual's condition or size changes, other components or accessories may be ordered and the chair reconfigured to meet the evolving needs of its user.

Warnings, cautions and contraindications that apply to the use of WTORS are detailed in the user's manual supplement, included in Appendix A.

#### **COMPARISON OF DEVICE CHARACTERISTICS TO PREDICATE(S):**

This device has the same technological and performance characteristics as the predicated devices. There are no new issues of safety or efficacy introduced by the bus transport models of the Zippie Quickie, or Breezy Series wheelchairs, other than the safe and effective performance of the wheelchair securement hardware. The safety of the occupant is controlled by the independent occupant restraint system. The chair-related issues of safety for the occupant during a crash are related to the structural integrity and travel of the chair. The travel of the chair is determined by 1) the chair securement points, and 2) the performance of the WTOR (not our product). The wheelchairs made by Sunrise Medical have been thoroughly tested and have been shown to sustain the forces of a frontal impact crash test acceptably. The wheelchairs can be used in bus transport if they have the securement hardware, proper product labeling and are properly secured to the vehicle.



Food and Drug Administration  
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Rockville MD 20850

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

NOV 20 1997

Re: K973673  
ZIPPIE, BREEZY, and QUICKIE Series Wheelchairs  
Regulatory Class: I  
Product Code: IOR  
Dated: September 16, 1997  
Received: September 26, 1997

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.

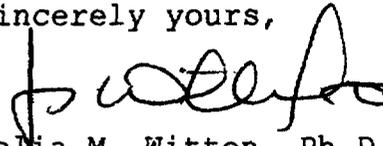
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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### 12.2 Indications for Use

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 Immobilizing    |
| Hemiplegic     | Muscular Dystrophy    | or debilitating condition |

Claim being added:

A wheelchair with the Bus Transport option, may be used for motor vehicle transportation, with the use of Wheelchair tiedown and occupant restraint systems (WTORS) that meet the requirements of SAE J2249.

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

Device name: MECHANICAL WHEEL CHAIRS

ZIPPY, BREEZY AND QUICKIE SERIES

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR801.109)

Over-the-counter use

*[Handwritten Signature]*  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number 14973673

*[Handwritten mark]*