13.0 510(k) SUMMARY OF SAFETY AND EFFICACY

K983639

Submitter: Rebecca Andersen
Date: 10/14/98

OCT 26 1998

Name(s) of the device(s):

Zippie GS

Identification of predicate device(s):

Quickie Kidz
Zippie
Zippie 2
Action Allegro
Action Comet

Description of the device:

Zippie GS wheelchairs are light weight, low maintenance, manual chairs, which are intended to provide mobility based on an individual users' needs and capabilities. They are available in a range of sizes (dimensions) to allow fit to a particular user.

The key change covered by this submission is the addition of optional growing solid seat and growing adjustable back. Individuals who use these wheelchairs benefit from the use of different seat cushions and back shapes as required by their individual postures and level of disability.

The addition of an optional growing solid seat facilitates the use of various cushions. The seat has been designed to offer a low cost support for these cushions. By being able to "grow" with the frame as it is adjusted in width and depth to accommodate change in the client's posture, dimensions or condition, the cost of these changes is reduced.

The addition of an optional growing adjustable back upholstery provides users the ability to adjust the contours of the upholstery by adjusting the length of individual straps at various contact points on the trunk. The back is also adjustable in height to match the height of various clients and their need for various degrees of posterior trunk support. The individuals straps also allow for adjustment of the depth of contour or "hammocking" of the back. This allows the client to adjust for lateral support of the trunk. The back has been designed to offer a low cost means for the adjustment of the aforementioned supporting shapes. Additionally by being able to "grow" with the frame as it is adjusted in width to accommodate change in the client's width, the cost of these changes is reduced.

When couple with the adjustment of the following performance factors the users function and comfort can be enhanced.

PERFORMANCE FACTORS

The impact of each adjustment has a different performance implication for the rider.

Camber	Camber adjustments range from 0 to 6 degrees
Wheel position	Rear wheels are set back to increase the wheelchair base. This improves stability. Wheelchairs may be susceptible to tipping over backwards. Sunrise recommends the use of anti tip tubes.
Wheel Base orTrack Width	Currently adjustable over a 4 inch range, a wider wheel base increases stability. Width can be adjusted to weigh gain or other environmental changes to allow enough space between the rider and the wheel.
Caster height.	Caster fork allows adjustments to be made ranging from +/-1 inch
Back Rest Angle	Adjustable from 78 degrees to 120 degrees. This angle is adjusted for need or comfort.
Seat Angle or Squeeze	Adjustable squeeze from 0 - 2 inches
Center of Gravity	The balance point. Different for each individual occupying a chair. This adjustment is made by the rider to his personal sense of balance, and reactivity. Center of gravity is adjusted by changes to axle position, seat angle, seat depth (weight distribution) and backrest angle

These factors are interrelated and must be adjusted to complement each other to tune the chair performance.

These adjustments are routinely made today, and usually require disassembly and the exchange of one part for another with different dimensions or geometry.

The predicate devices including the existing Zippie & Quickie product lines allow users to make adjustments to these factors as well as the wheelchairs seat and back support surfaces.

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 10 to 18 inches. Specific configuration includes chair accessories and desired use or 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 users needs. As the individuals condition or size change, other components or accessories may be ordered and the chair reconfigured to meet the evolving needs of its user.

Zippie GS wheelchairs consist of typical components found on most wheelchairs, such as backrest, seat frame, cushion, footrest and casters. Options include growing solid seat and growing adjustable back. Accessories include items such as elevating leg rest, armrests, positioning belts, backpacks, seat pouches, oxygen tank holders, IV poles, etc.

Many of these components may become 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.

The optional growing solid seat and growing adjustable back is much like those used in competitive products.

The chairs have excellent performance indoors and are very good outdoors over surfaces that are firm and free of large obstacles and long steep inclines. That makes them an ideal maneuverable, light duty, light weight "Get out there chair".

The feature/option will be employed to upgrade the performance of existing devices manufactured by Sunrise Medical Mobility Products Division.

COMPARISON OF DEVICE CHARACTERISTICS TO PREDICATE(S):

Testing:

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

Determination of Static Stability	Pass
Overall Dimensions, Mass and Turning Space	Pass
Seating Dimensions	Pass
Static Impact and Fatigue Strength	Pass

Safety:

An analysis of complaints against Quickie manual 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. 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.

Efficacy

Articles are being provided on the use and efficacy of mechanical reclining wheelchairs. See Appendix C.

510(k) number:

Not assigned at the writing of this summary

Conclusion:

The Zippie GS Wheelchair model shares performance features and technology with a number of devices already legally marketed within the United States. The design changes that allow the user to adjust the back angle of the chair do not introduce issues of safety or efficacy. This feature introduces comfort and convenience. Therefore, the Breezy 510 Reclining wheelchair option is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1998

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

Re: K983639
Trade Name: Zippie GS, Model #EIZGS
Regulatory Class: I
Product Code: IOR
Dated: October 14, 1998
Received: October 16, 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.

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,

for 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

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 suc as:

Arthritis	Tetraplegic	Multiple Sclerosis
Amputee	Quadriplegic	Polio
Paraplegic	Spina Bifida	Geriatric conditions
Cerebral Palsy	Head Injury or Trauma	And other immobilize-
Hemiplegic	Muscular Dystrophy_	ing or debilitating conditions

A wheelchair with Bus Transport Option may be used for motor vehicle transportatio with the use of wheelchair tie down and occupant restraint system (WTORS) that me the requirements of SAE J2249

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

Device name: Zippie GS

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR801.109)

Over-the-counter use

Over-the-Counter Use X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983639