

13.0 510(k) SUMMARY OF SAFETY AND EFFICACY

AUG 12 1997

K972797

Submitter: Rebecca Andersen

Date: July 23, 1997

Name(s) of the device(s):

Tool-less Wheel Chair (To be renamed at market release)

Identification of predicate device(s):

Quickie's	GPS
Invacare's	A-4
Everest & Jennings'	Barracuda

Description of the device:

The tool-less wheel chair 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, and is adjustable in various ways, including: The key change covered by this submission is the ability to make several routine adjustments quickly, and without the need for additional parts or the use of tools. These typical routine adjustments include:

CHAIR STANCE

Camber	The angle of the wheels with respect to the side frame of the chair
Forward / aft	wheel position Axle location with respect to front/back of chair
Toe in/ toe out	The amount by which the distance between the front of the two rear wheels varies from the distance at the back.
Track Width	The distance between the wheels
Caster height	Adjusting the relative height of the front of the chair or adjusting to accommodate for rear camber adjustments and/or seat height.

All of these factors are interrelated and must be adjusted to complement each other to tune the chairs performance.

RIDER POSITION

Back Rest Angle	The angle of the back of the chair with respect to the side frame
Squeeze	The angle or slope of the seat with respect to the side frame

The combination of chair stance and rider position determine the center of gravity, a factor on the performance of the chair.

Center of Gravity	The center of Mass (the point at which the entire weight of a body may be considered as concentrated so that if supported at this point the body would remain in equilibrium in any position)
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PERFORMANCE FACTORS

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

Camber Currently adjustable to five positions ranging from zero to sixteen degrees the camber is easy to adjust as the rider lines up color coded marks to obtain the desired angle. Wheels straight up (0 degrees) provides the most narrow chair, but is less stable. As the top of the wheels are brought closer together, the bottoms become farther apart. This increases the wheel base, and creates improved stability. It also allows the chair to turn with less effort. A rider may want stability on the basketball court, and maneuverability in the office. To adjust to changing needs, he may set the camber high for the basketball court, low to maneuver tight office spaces, and mid range for daily home use.

Forward / aft wheel position Currently adjustable over a four inch range, placement of the rear wheels in the forward position on the splined frame section makes the chair very responsive and maneuverable. However, it also makes it very susceptible to tipping over backwards. Sunrise recommends the use of anti tip tubes when the rear wheels are in the forward positions.

Toe in/ toe out Usually desired to be neutral for best alignment. Alignment is built into the locked variable positions. It is also tied to caster adjustment. (Casters must be set to same height or chair will be misaligned.)

Wheel Base or Track Width Adjustable over a four 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. Adjusted to keep the frame level as the other adjustments are made.

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

Back Rest Angle Adjustable from 16 degrees forward to 8 degrees back, the angle from the seat to the backrest upholster. This angle is usually adjusted when the squeeze is adjusted.

Seat Angle or Squeeze Any one of four preset settings, changing the squeeze fine tunes the ride height for propelling and reach. This adjusts the comfort level of the user, and also raises or lowers the center of gravity.

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 wheel width, forward/aft axle position, seat angle, seat depth (weight distribution) , and caster height.

Chairs are configured to customer orders when sold. Configuration to order allows flexibility. Features such as width, depth, and back height are specified. 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 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.

Tool less wheelchairs consists of typical components found on most wheelchairs, such as backrest, seat frame, cushion, footrest and casters. Accessories include items such as 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 chairs have excellent performance indoors and are very good outdoors over surfaces that are firm ad free of large obstacles and long steep inclines. That makes them an ideal maneuverable, light duty, light weight "Get out there chair".

Warnings, cautions and contraindications are detailed in the users manual.

COMPARISON OF DEVICE CHARACTERISTICS TO PREDICATE(S):

The chairs have similar performance features, the Tool-less allows chair adjustment quickly, any time, any where, with no tools required.

These adjustments are routinely made today, but usually require disassembly and often the exchange of one part for another with different dimensions or geometry. The tool-less wheel chair achieves the same goal through the use of self contained, variable position, adjustments.

The predicate devices including the Quickie GPS allow the dealer to make adjustments to these factors relating to chair stance and rider position. The tool-less chair's construction allows these routine adjustments, without tools.

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
General Requirements for Safety	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 power wheelchairs. See Appendix C.

510(k) number:

Not assigned at the writing of this summary

Conclusion:

The Tool-less Wheel Chair, 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 his chair without the use of tools do not introduce issues of safety or efficacy. They introduce convenience. Therefore, the Tool-less wheel chair is substantially equivalent to the predicate devices.



Food and Drug Administration
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Ms. Rebecca Andersen
Vice President, Quality and Regulatory Affairs
Sunrise Medical
7477A East Dry Creek Parkway
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AUG 12 1997

Re: K972797
Tool-Less Wheel Chair
Regulatory Class: I
Product Code: IOR
Dated: July 24, 1997
Received: July 28, 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.

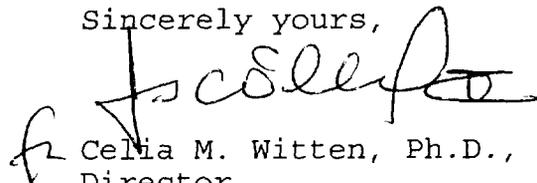
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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". The signature is written in a cursive style with a large initial "C" and "W".

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 such as :

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|----------------|-----------------------|-----------------------|
| 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 |
| | | condition |

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

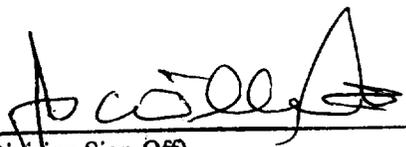
Device name: Tool-Less Wheelchair

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR801.109)

Over-the-counter use

~~Over-the-Counter Use~~ Over-the-Counter Use


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K972797