

**13.0 510(k) SUMMARY OF SAFETY AND EFFICACY**

Submitter: Rebecca Andersen

Date: December 18, 1997

R 974820

JAN 27 1998

Name(s) of the device(s):

Breezy Series

Identification of predicate device(s):

Sunrise	Breezy Family
Invacare's	9000
Everest & Jennings'	Universal
Everest and Jennings	EZ LITE

**Description of the device:**

The Breezy series wheelchairs are light weight manual chairs. These chairs 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, and is adjustable in various ways, including: The key change covered by this submission is the addition of a reclining back model to the Breezy product line.

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.

Breezy wheelchairs with or without the reclining back option, 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 and free of large obstacles and long steep inclines. That makes them an ideal maneuverable, light weight "Get out there chair".

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

JAN 27 1998

Re: K974820  
Breezy Series  
Regulatory Class: I  
Product Code: IOR  
Dated: December 16, 1997  
Received: December 23, 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.

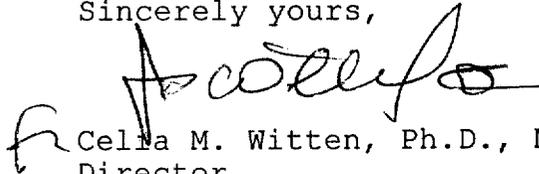
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Rebecca Andersen

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,



Cella 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:

- |                |                       |                       |
|----------------|-----------------------|-----------------------|
| 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             |

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

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

Device name: Breezy Series

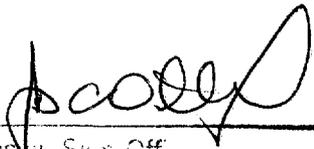
Which today consist of :

- Breezy 500
- Breezy 510
- Breezy 510 Recliner
- Breezy 600

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use (per 21 CFR801.109)

Over-the-counter use

  
 (Division Sign Off)  
 Division of Restorative Devices  
 510(k) Number RA7482



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 27 1998

Mr. Zhou Shun Kao  
Wenzhou Hindar Optical Co., Ltd.  
No. 46-5 Liming Mid Road  
Wenzhou City, China

Re: K974861  
Trade Name: Non-prescription Sunglasses  
Regulatory Class: I  
Product Code: 86 HQY  
Dated: December 17, 1997  
Received: December 29, 1997

Dear Mr. Kao:

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 requirements, 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.

Page 2 - Mr. Zhou Shun Kao

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) 594-4613. 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. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K974861

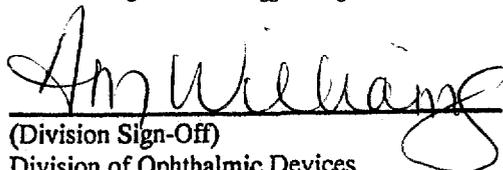
Device Name: Sunglasses

Indications For Use:

*Sunglasses (nonprescription) are devices that consist of spectacle frames or clips with absorbing, reflective, tinted, polarizing, or photosensitized lenses intended to be worn by a person to protect the eyes from bright sunlight but not to provide refractive corrections. This device is usually available over-the-counter.*

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number K974861

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use XXX

(Optional Format 1-2-96)