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510(k) SUMMARY

Submitter's Name: FreeRider Corporation
No. 181, Ta-Te 1st Road
Kang Shan Town, Kaohsiung
Taiwan R.O.C.
886-7-622-3093

Date summary prepared: October 6, 2003

Device name:

Proprietary name:	FR168W Powered Wheelchair
Common or usual name:	Power chair.
Classification name:	Powered wheelchair, Class II, 21 CFR 890.3860.

Legally marketed device for substantial equivalence comparison:

Jazzy Power Chair submitted by Pride Health Care, Inc. and cleared for marketing under 510(k) #K945936.

Description of the device:

The FR168W Powered Wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The product has a base with six wheels, an adjustable seat with armrests, an adjustable footrest, and a controller attached to one armrest. The controller allows the rider to control the movement of the chair. The chair can be disassembled for transport and is provided with a battery charger.

Intended use of device:

The FR168W Powered Wheelchair provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

Technological characteristics:

The device features and use parameters of the FR168W Powered Wheelchair and the Jazzy Power Chair are very similar. Both are battery operated, have two motors, and have automatic braking systems. The controllers regulate similar features for both wheelchairs. Battery chargers and instructions for their use are supplied with both chairs. Use parameters are very similar as well, with minor variations in such areas as turning radius and maximum speed.

Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles*, July 1995, were conducted and the results included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

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SECTION 3 - INTENDED USE

Intended use of device:

The FR168W Powered Wheelchair provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

Intended use of predicate device:

The intended use of the Jazzy Power Chair is given in the Owner's Manual "Your power chair is a state-of-the-art life-enhancement device designed to increase mobility."

Comparison:

The intended uses of the two products are identical.

Labeling:

The intended use of the FR168W Powered Wheelchair is on page 4 of the Owner's Manual found in Appendix II. The intended use of the Jazzy Power Chair is on page 6 of the Owner's Manual found in Appendix V.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2003

FreeRider Corporation
C/o Mr. Robert S. McQuate
R.S. McQuate and Associates, Inc.
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K033370
Trade/Device Name: FR168W Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: October 16, 2003
Received: October 21, 2003

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K033370

Device name: FR168W Powered Wheelchair

Indications for Use: The FR168W Powered Wheelchair provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

for Mark N Milhern

Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033370