7/23/97

K971388

510(k) SUMMARY

Submitter's Name: Freerider USA, Inc.
160 N.E. 20th Drive
Hillsboro, OR 97124
(503) 640-8924

Date summary prepared: March 14, 1997

Device name:

Proprietary name:	Freerider™ FR168-4
Common or usual name:	Electric scooter.
Classification name:	Motorized three-wheeled vehicle, Class II, 21 CFR 890.3800.

Legally marketed device for substantial equivalence comparison:

Shoprider™-TE889 submitted by Pride Health Care, Inc. and cleared for marketing under 510(k) #K920654.

Description of the device:

The Freerider Model FR168-4 is a motorized four-wheeled scooter which is battery operated. It consists of a platform which connects the four wheels, an adjustable tiller, and a seat for the rider. It is driven by the rider using hand controls located at the top of the tiller. It can be disassembled into five parts for transport in a car trunk. It is provided with a battery charger.

Intended use of device:

The device 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 Freerider and Shoprider scooters are very similar. Both are battery operated, have 0.9 horsepower motors, and have regenerative brake systems. Batteries and battery chargers are similar and are provided with the scooters. Use parameters are very similar, varying only in minor parameters such as the curb climbable by the respective scooters.

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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Robert S. McQuate, Ph.D.
R.S. McQuate & Associates
Representing Freerider USA, Inc.
2322 Douglas Drive
Eugene, Oregon 97405

JUL 23 1997

Re: K971387
Freerider™ Model FR510-F
K971388
Freerider™ Model FR168-4
Regulatory Class: II
Product Code: INI
Dated: July 9, 1997
Received: July 14, 1997

Dear Dr. McQuate:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are 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 devices, 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.

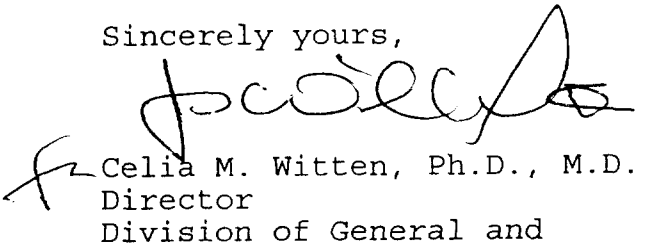
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Enclosures

Indications for Use Statement

510(k) Number (if known): K971388

Device name: Freerider FR168-4

Indications for Use:

The Freerider Model FR168-4 is a motorized scooter which 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971388

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