

K971387

**510(k) SUMMARY**

JUL 23 1997

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

Date summary prepared: March 14, 1997

Device name:  
Proprietary name: Freerider<sup>TM</sup> FR510-F  
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<sup>TM</sup>-TE889 submitted by Pride Health Care, Inc. and cleared for  
marketing under 510(k) #K920654.

Description of the device:  
The Freerider Model FR510-F 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).



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 (Pre-market 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

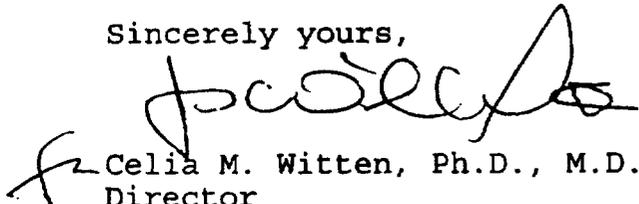
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): 971387

Device name: Freerider FR510-F

**Indications for Use:**

The Freerider Model FR510-F 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

OR

Over-The-Counter Use \_\_\_\_\_