K110165

510(k) SUMMARY

SEP 30 2011

Submitter's Name: JEFFREY L DAVIS
FreeRider Corporation
No.22, Bengong 5th Road, Kang-Shan Town
Kaohsiung County 820, Taiwan

Date summary prepared NOVEMEBR 15st, 2010

Device name:

Proprietary name: Freerider Luggie

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:

Tzora Active Systems Ltd –Easy Travel Elite submitted by Tzore Active Systems , Inc, Kibbutz , Tzora

Description of the device:

The Freerider Model Luggie is a motorized three wheeled scooter which is battery operated. It consists of a platform which connects the three wheels, an adjustable tiller, and seat for the rider. It is driven by the rider using hand controls located at the top of the tiller. It can be simply folds under five steps into one unit for transport in a car trunk. It is provided with a battery & a battery charger.

Intended use of device:

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

Technological characteristics:

The device features and use parameters of the Freerider and Tzora scooters are very similar. Both are battery operated, have 0.1 horsepower motors, and have regenerative brake systems. Batteries capacity and battery chargers are similar and are provided with the scooters. Use parameters are very similar, varying only in minor parameters such as the grade climbable by the respective scooters.

Testing conducted:

Tests listed in the *Guidance Document for the preparation of market Notification [510(k)] Applications for Mechanical and powered wheelchairs, and Motorized Three Wheeled Vehicles,* July1995, 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 30 2011

FreeRider Luggie Scooters, Inc.
% Diagnostic Medical Consultant
Mr. Jeffrey L. Davis
4500 Country Glen Court
Riverside, CA 92505

Re: K110165
Trade/Device Name: FreeRider Luggie
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: August 24, 2011
Received: August 24, 2011

Dear Mr. Davis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Statement

510(k) Number (if known): K110165

Device name: Freerider Luggie

Indications for Use:

The Freerider Model Luggie is a motorized scooter which provides transportation for an elderly or disabled person. It can be 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110165

Prescription Use_____ **OR** **Over-The-Counter Use** ✓

(Per 21 CFR 801.109)