



Food and Drug Administration  
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September 10, 2015

Freerider Corporation  
c/o Michael Chen  
R&D Department and Assistant Vice President  
No. 22, Bengong 5th Road Kang-Shan Dist  
Kaohsiung City, 820, Taiwan, R.O.C.

Re: K151944

Trade/Device Name: Luggie Super  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized three-wheeled vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: May 31, 2015  
Received: July 14, 2015

Dear Mr. Chen:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**Michael J. Hoffmann -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151944

Device Name

Luggie Super

Indications for Use (Describe)

The FR-L05 (Luggie Super) provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

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### **1. Contact Details**

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Contact Name: Michael Chen  
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Date Prepared: May 31, 2015

### **2. Device Name**

Trade Name: Luggie Super  
Common Name: Electric scooter  
Classification Name: Motorized three-wheeled vehicle; INI; 890.3800

### **3. Legally Marketed Predicate Device(s)**

510(k) Number	Product Code	Trade Name	Manufacturer
K110165	INI	Freerider FR 168-4(IT) Luggie	Freerider Corp.

### **4. Device Description**

The FR-L05 (Luggie Super) is a battery-powered, three-wheeled scooter intended to provide mobility for elderly or disabled individuals in a variety of indoor and outdoor settings. The FR-L05 (Luggie Super) is meant to be used by a single rider weighing up to 360 pounds. The scooter is rear-wheel drive and has electric, regenerative electromechanical brakes. It has an adjustable seat that has several height adjustments. The steering and user controls are provided on the steering tiller/handlebars for ease of use by the rider. Steering is controlled simply by turning the handlebars in the desired direction. There are two thumb levers, and speed knobs on the tiller console to control movement speed of the scooter.

The FR-L05 (Luggie Super) has a controller and 1 lithium battery. The controller is used

Freerider FR-L05(Luggie Super)  
510(k) Notification

on a number of other scooters that have been previously cleared. There is also an off-board battery charger, which has also been previously cleared. The specification of battery charger is the same as the predicate device, Freerider Luggie FR168-4(IT) (K110165).

## **5. Intended Use/Indications for use**

The FR-L05 (Luggie Super) provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

## **6. Substantial Equivalence Comparison**

The FR-L05 is substantially equivalent to the Freerider Luggie FR168-4(IT) (K110165).

The device features of the FR-L05 and the Luggie FR168-4(IT) (K110165) are very similar. Both are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar. The difference are as follows. The maximum weight that the FR-L05 can carry is greater, the spacing between the wheels is wider, and that it has a bigger seat.

## **7. Non-clinical Testing**

Electromagnetic interference testing was conducted to IEC 6100-4-2, IEC 6100-4-3, IEC 6100-4-8, EN 12184:2009, EN 55011:2010, and EN55022. ISO 7176 testing to multiple sections; Section 1, Section 2, Section 3, Section 4, Section 5, Section 6, Section 7, Section 8, Section 9, Section 10, Section 11, Section 13, Section 14, Section 15, Section 16, and Section 21 was conducted. As well as ISO 10993 and IEC60601-1. Additional bench testing related to ground current leakage and summary matrix testing was also conducted. The FR-L05 (Luggie Super) passed all testing.

## **8. Clinical Testing**

No clinical testing is included in this submission.

## **9. Technological Characteristics**

The device features of the FR-L05 and the FR168-4(IT) (K110165) are very similar. Both are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar. There are some differences between the FR-L05 and the FR168-4(IT) (K110165). One is that the FR-L05 is heavier and it can carry a heavier user. Widening of the base to get a better stability. None of these differences raises new issues of safety and effectiveness.

## **10. Conclusion**

The safety and effectiveness of the FR-L05 (Luggie Super) was demonstrated by the testing in compliance with national and international standards. The intended use, basic technology, and many features of the FR-L05 are similar to the predicate device. No new issues of safety and effectiveness is raised by the differences between the FR-L05 and FR168-4(IT) (K110165).