DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 20, 2017

Freerider Corporation
Michael Chen
R&D Department and Assistant Vice President
No. 22 Bengong 5th Road
Kang-Shan District, TW

Re: K160139
Trade/Device Name: Luggie Chair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 7, 2017
Received: March 17, 2017

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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160139

Device Name
Luggie Chair

Indications for Use *(Describe)*
The FR-W04 (Luggie Chair) 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.

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510(k) Summary
K160139

1. Contact Details

Applicant Name: Freerider Corporation
No. 22, Bengong 5th Road
Kang-Shan Dist, Kaohsiung 820, Taiwan

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Date Prepared: Nov 03, 2015

2. Device Name

Trade Name: Luggie Chair

Common Name: Powered Wheelchair

Classification Code: ITI

Regulation Number: 21 CFR 890.3860

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K033370	ITI	Freerider FR 168-W Power chair	Freerider Corp.
K151944	INI	Freerider FR-L05 Luggie Super	Freerider Corp.

4. Device Description

The FR-W04 (Luggie Chair) is a battery-powered, four-wheeled electric wheelchair intended to provide mobility for elderly or disabled individuals in a variety of indoor and outdoor settings. The FR-W04 (Luggie Chair) is meant to be used by a single rider weighing up to 360 pounds. The wheelchair is rear-wheel drive and has electric, regenerative electromechanical brakes. The steering and user controls are provided on the armrest for ease of use by the rider. Steering is

controlled simply by turning the top controller in the desired direction. There is one lever, and speed knobs on the top controller to control movement speed of the wheel chair. The specification of control method is the same as the predicate device, Freerider FR168-W Power Chair (K033370).

The FR-W04 (Luggie Chair) has a controller and one lithium battery. There is also an off-board battery charger, which has also been previously cleared. It has an adjustable seat that has several height adjustments. The specification of battery charger and adjustable seat is the same as the predicate device, Freerider Luggie Super FR-L05 (K151944).

5. Intended Use/Indications for use

The FR-W04 (Luggie Chair) provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

6. Substantial Equivalence Comparison

	K160139 (subject device)	K033370 (predicate)	K151944 (predicate)
General Device Characteristics			
Manufacturer	Freerider	Freerider	Freerider
Model	FR-W04 (Luggie Chair)	FR168W	Luggie Super
Indications for Use	The FR-W04 (Luggie Chair) provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.	The fr168w powered wheelchair provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.	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.
Framework	Folding seat and		Folds for

	footrest Adjustable height		transport
Overall Dimensions			
Length (in)	37.44	32	39
Width (in)	23.86	22	20.7
Height (in)	30.11-33.11	40 (46 with headrest)	35.7
Seat Dimensions			
Width (in)	17		16.9
Depth (in)	15.43		13.2
Height (in)	8.98		17.3
Folded Dimensions (if applicable)			
Length (in)	31.73		27.76
Width (in)	23.86		
Height (in)	17 (w/o armrest)		
Wheelchair Weight			
With batteries	76.56 lbs.	84.5 lbs.	67.1 lbs.
Without batteries	71.72 lbs.		62.26 lbs.
Controller	Dynamic 40A	P&G VSI Controller	Rhino R-series 50
Motor (include output)	2 24V	2 0.339hp	1
Batteries			
Quantity	1	2	1
Type	Lithium 24V, 10.5Ah	12V, U-1 sealed	Lithium 24V 10.5 Ah

Range per Charge	8.19 mi (198 lbs.) 6.31 miles (360 lbs.)	25 mi	10.5 mi (198 lbs) 7.25 miles (360 lbs)
Charger	Off board Switching Mode AC-DC 100V~240V 50/60Hz Output :5A	Onboard standard, off board optional 4A 110V	Off board Switching Mode AC-DC 100V~240V 50/60Hz Output :5A
Actuator	Dynamic LiNX 40A module		
Brake	Electronic regenerative, electromechanical	Electronic regenerative	Electronic regenerative, electromechanical
Minimum braking distance			
Forward (in)	73.14	44.8	75.9
Reverse (in)	30.87		47.2
Max speed			
Forward	4 mph	4 mph	4 mph
Reverse	2.4 mph	3.8 mph	2.4 mph
Rear Wheels (in)	2 x 8	10	2 x 7
Castors (in)	2 x 7	8	2 x 6
Anti-tip wheels	2.55 in	6 in	Yes
Max Weight Capacity	360 lbs.	300 lbs.	360 lbs.
Curb Climbing ability	0.98 in		
Ground clearance	1.22 in		2.13 in
Minimum Turning Radius	30.7 in	26 in	41.3 in

Maximum Incline (°)	6	5	6
Footplates	Foldable		
Armrest Type	Fold up		
Warranty	Provided		

The control method of the FR-W04 (Luggie chair) is substantially equivalent to Freerider FR168-W (K033370).

The device features of the FR-W04 (Luggie Chair) and the FR168-W (K033370) are similar. Both are electric wheelchairs that are battery operated and have automatic breaking systems. Operating mode and interface are very similar, the control lever is mounted on an armrest, and directional control is the same as FR168-W (K033370). The differences are as follows: The FR-W04 has an adjustable seat that has several height adjustments. The front and rear wheels are 7" and 8" respectively, smaller than that of the FR168-W (K033370).

The battery with charger and adjustable seat features on the FR-W04 (Luggie Chair) is substantially equivalent to that of the FR-L05 Luggie Super (K151944). The device features of the FR-W04 (Luggie Chair) and the FR-L05 Luggie Super (K151944) are similar. Both are battery operated and have automatic breaking systems. The charger and adjustable seat is the same between the two devices. The differences are as follows: The control lever of the FR-W04 is mounted on the armrest. The FR-W04 does not have a front handle bar and front chassis.

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 10993-1, ISO 10993-5, ISO 10993-10 and IEC60601-1. Additional bench testing related to ground current leakage and summary matrix testing was also conducted. The FR-W04 (Luggie Chair) passed all testing.

8. Clinical Testing

No clinical testing is included in this submission.

9. Conclusion

The safety and effectiveness of the FR-W04 (Luggie Chair) was demonstrated by the

testing in compliance with national and international standards. The intended use, basic technology, and many features of the FR-W04 (Luggie Chair) are similar to the predicate device. No new issues of safety and effectiveness are raised by the differences between the FR-W04 (subject device), FR168-W (K033370), and FR-L05 Luggie Super (K151944). Therefore, the subject device is substantially equivalent to the predicate devices.