



Food and Drug Administration
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September 22, 2015

Heartway Medical Products Co., Ltd.
Jen, Ke-Min
Official Correspondent
No.6 Road 25, Taichung Industrial Park,
Taichung City, 40850
Taiwan

Re: K150987
Trade/Device Name: Heartway Power Mobility Scooter, BRIO S19
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 5, 2015
Received: August 19, 2015

Dear Jen, Ke-Min:

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,

Carlos L. Pena -S 

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)

K150987

Device Name

Heartway Power Mobility Scooter, BRIO S19

Indications for Use (Describe)

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

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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5. 510(k) SUMMARY

Submitter's Name: ***HEARTWAY Medical Products Co., Ltd.***

No.6, Road 25, Taichung Industrial Park,
Taichung, 40850, Taiwan, ROC

Date summary prepared: August 9, 2015

Device Name:

Proprietary Name: HEARTWAY Power Mobility Scooter, BRIO S19

Common or Usual Name: POWERED SCOOTER

Classification Name Motorized Three-Wheeled Vehicle, Class II,
21 CFR 890.3800

Product Code: INI

Company contact person: Mr. Tien-hsing Yang (Email: yhead0722@hotmail.com)

Official Correspondent: Dr. KE-MIN JEN (email: ceirs.jen@msa.hinet.net)

TEL: 886-3-5208829, FAX: 886-3-5209783

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Description of the device:

- BRIO S19 power scooter is battery powered and configured with four solid wheels, a seat, a turning tiller column, a upper panel control, a main frame, a cross bar and an anti-tipper.



- BRIO S19 power scooter is operated by two rear wheels as the drive wheels and two front wheel as the steering wheel, using the upper panel control to control the turning tiller column mechanism to control the front wheel as the power scooter steering direction mechanism. Upper panel control is able to control driving forward, driving backward, speed control. The main frame is equipped with a rear bumper to allow the scooter to sustain an impact without damage to the power scooter safety system. BRIO S19 power scooter maximum weight capacity is 220 lbs (100 kg), and BRIO S19 power scooter maximum speed is 5 mile/hr (8 km/hr).

- The following surfaces are recommended not to operate on:
 - ◆ Sand surface
 - ◆ Wet or icy surface
 - ◆ Road maintenance hole metal cover
 - ◆ Avoid going up multiple steps.
 - ◆ Avoid using escalators. Use the elevator.
 - ◆ Too steep incline over 6 degrees.
 - ◆ Ground clearance to battery 60 mm / 2.3”
 - ◆ Curb climbing ability 45 mm / 1.7”

Performance Testing:

- (1) EMC Test: ANSI / RESNA WC-2:2009 (Section 21) Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods
 - CISPR 11:2009
 - IEC61000-4-2: 2008
 - IEC61000-4-3: 2006+A1:2008+A2:2010
 - IEC61000-4-4:2004
 - IEC61000-4-5:2005
 - IEC61000-4-6:2008
 - IEC61000-4-8:2009
 - IEC61000-4-11:2004



- (2) ISO 7176-1 Wheelchairs - Part 1: Determination of static stability, 1999.
- (3) ISO 7176-2 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs, 2001.
- (4) ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2012.
- (5) ISO 7176-4 Wheelchairs - Part 4: Energy consumption of electric wheelchairs for determination of theoretical distance range, 2008.
- (6) ISO 7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space, 2008.
- (7) ISO 7176-6 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs, 2001.
- (8) ISO 7176-7 Wheelchairs - Part 7: Determination of seating dimensions - Definitions and measuring method, 1998.
- (9) ISO 7176-8 Wheelchairs - Part 8: Static, impact and fatigue strength for manual wheelchairs, 1998.
- (10) ISO 7176-9 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, 2009.
- (11) ISO 7176-10 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs, 2008.
- (12) ISO 7176-11 Wheelchairs - Wheelchairs - Part 11: Test dummies, 2012.
- (13) ISO 7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces, 1989.
- (14) ISO 7176-14 : Power and control system for electric wheelchairs, 2008.
- (15) ISO 7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling, 1996.
- (16) ISO 7176-16 Requirements and test methods for resistance to ignition of upholstered parts, 2012.
- (17) ISO 7176-21 : Requirements and test method electromagnetic compatibility of powered wheelchairs and motorized scooters, 2009.



Biocompatibility information

Patient contacting materials: Seat PVC material, Hand grip PVC material, Seat belt PVC material

We tested these patient contacting materials for compliance to the standards ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010. We provide the FDA Form 3654 for these standards.



HEARTWAY MEDICAL PRODUCTS CO.,LTD.

NO.6, ROAD 25, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN R.O.C. 408

TEL : 886-4-23580357 (Sales) · 23583232 (Rep) FAX : 886-4-23590786

Web : www.heartway.com.tw

E-mail : sales@heartway.com.tw



COMPARISON TABLE

Similarities

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE	Safety and effectiveness of subject device compared to the predicate device
BRAND NAME	HEARTWAY		Same brand
MANUFACTURER	HEARTWAY Medical Products Co., Ltd.		Same manufacturer
MODEL NO	S34	BRIO S19	Different model
510K NO	K101142	TBA	Different submission
SERIES	Lightweight Power Mobility Scooter Series	Power Mobility Scooter series	Lighter scooter weight design
INTENDED USE	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same intended use and target population
Weight limit	100 kgs / 220 lbs	100 kgs / 220 lbs	Same weight
Electronics controller	Penny & Giles S-Drive	Penny & Giles S-Drive	Same controller
Motor	3A 24V, 270W @1	3A 24V, 270W @1	Same motor type
Footplates	ABS	ABS	Same footplate material



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ITEMS	PREDICATE DEVICE	SUBJECT DEVICE	Safety and effectiveness of subject device compared to the predicate device
Suspension	Cross brace	Cross brace	Same
Back upholstery	Fabric	Fabric	Same
Wheel Lock	Push-to-Lock	Push-to-Lock	Same
Warranty	3 years: Main frame 1 years: Controller / gear motor / batteries w/o exhaustive and wear parts	3 years: Main frame 1 years: Controller / gear motor / batteries w/o exhaustive and wear parts	Same
Batteries			
Quantity	Two	Two	Same battery
Type	12Ah /12VDC	12Ah /12VDC	
Patient contacting materials	Seat PVC material Hand grip PVC material Seat belt PVC material	Seat PVC material Hand grip PVC material Seat belt PVC material	Same PVC materials

Differences:

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE	Safety and effectiveness of subject device compared to the predicate device
Overall dimension			
Overall length	995 mm / 39.0"	930 mm / 36.6"	Smaller dimensions
Overall width	490 mm / 19.3"	485 mm / 19.0"	
Overall height	940 mm / 37.0"	945 mm / 37.2"	
Armrest types	Flip-backward	No armrest	No armrest for subject device
Frame	Fixed / carbon steel	Fixed / Aluminum alloy	Lighter frame material
Seat dimension			
Seat width	570 mm / 22.5"	395 mm / 15.5"	Smaller dimensions
Seat height	408 mm / 16"	350 mm / 13.75"	
Rear wheels	8" x 3" solid x 2	8" x 2" solid x 2	Thinner tires
Front casters	8" x 3" solid x 2	7" x 1.6" solid x 2	Smaller tires
Turning Radius	950 mm / 37.4"	820 mm / 32.2"	Smaller radius
Ground clearance	70 mm / 2.8"	60 mm / 2.3"	Smaller clearance
Kerb climbing ability	50 mm / 2.0"	45 mm / 1.7"	Smaller kerb
Scooter weight	w/ batteries 43.6kgs / 96 lbs w/o batteries 36.6kgs / 81lbs	w/batteries 31.3kgs / 69 lbs w/o batteries 24.0kgs / 53 lbs	Smaller weight
Maximum speed	7.8 km/hr (4.875 mile/h)	8.0 km/hr (5.0 mile/h)	Larger speed
Incline	10 degrees	6 degrees	Smaller angle
Range per full charging	10~15 km / 6~9 miles	18 km / 11.25 miles	Longer cruise rang



Battery Charger	External (off-board) charger	External (off-board) charger	Same type
Voltage output	24VDC (UL E241359)	24VDC (UL E201162)	different models with same voltage output
model	4C24020A	4C24050A	
Biocompatibility	ISO 10993-1:2009 ISO 10993-5:2009	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	More testing

COMPARISON DISCUSSION

The intended uses and the target populations for the two devices are the same. The weight limit 100kgs / 220lbs, P&G S-Drive electronic controller, the type of motor and batteries, suspension of cross brace, footplates, warranty of the components, the back upholstery material, and patient-contacting materials are the same. The back upholstery fabric passed the resistance ignition test in accordance with ISO 7176-16.

The electronic systems for two devices are the same and passed the UL certifications. Though battery charger and the competent components are different, they all passed the UL certifications. Thus the same safety levels for the two devices are assured.

There is one more biocompatibility testing ISO 10993-10:2010 for the subject device than the predicate device. This can ensure more safety and biocompatibility for the users.

There is no armrest for the subject device since it is designed for lighter and faster ways. Armrest is not a safety factor for users. No armrest leads to less weight and more compact size for BRIO S19 and the safety and effectiveness concerns are also ensured.

The major differences between the subject device and the predicate device are scooter weights and dimensions, due to the subject device BRIO S19 using lighter mainframe material of aluminum alloy than the carbon steel material used by predicate device. But both carbon steel and aluminum alloy materials all passed the strength and fatigue tests. The safety and effectiveness concerns are ensured.



We know work equals to force ($= \text{weight}/9.8$) times distance. The motor powers ($=\text{work}/\text{second}$) and the batteries are the same. So the subject device has larger cruise range per full charging than the predicate device since the subject device has lighter weight. In addition, it is also known that power equals to force times speed. For the same power, the force ($\text{weight}/9.8$) is inversely proportionally to the speed. So the subject device has larger maximum speed 8.0 km/hr (5.0mile/h) than the predicate device 7.8 km/hr (4.88 mile/hr) since BRIO S19 has lighter weight. In order to stand the larger scooter weight, the predicate device must have larger rear wheels and castors. For a larger rear wheels and castors of the predicate device, the turning radius is surely larger. This also leads to larger ground clearance and larger kerb climbing ability for the predicate device.

For a larger overall height and smaller seat height for the subject device, the center of weight with loaded user must be higher and the subject device must be less stable when moves on an incline. So; incline capabilities for subject device is 6° and for predicate device is 10° . But the safeties of both devices moving on the maximum inclined slopes were ensured by the ISO 7176-1 and ISO 7176-2 tests.

Despite of the above differences, the two devices all completed the performance tests in accordance with ISO 7176 series standards and the ANSI / RESNA WC 2, Section 21 for the EMC test. There are no safety and effectiveness aspects concerned. Thus, the two devices are substantially equivalent.

CONCLUSIONS

The subject device, HEARTWAY Power Mobility Scooter, BRIO S19, is as safe and effective as, and functions in a manner equivalent to the predicate device, HEARTWAY Lightweight Power Mobility Scooter S34. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.