



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

November 25, 2015

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

Re: K151656  
Trade/Device Name: HEARTWAY Power Mobility Scooter, Cutie S17  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized Three-Wheeled Vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: October 19, 2015  
Received: October 28, 2015

Dear Dr. Ke-Min Jen,

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 and Part 809); 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 and Part 809), 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,

**William J. Heetderks -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)

K151656

Device Name

Heartway Power Mobility Scooter, Cutie S17

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*



## 5. 510(k) SUMMARY of the Safety and Effectiveness

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

No.6, Road 25, Taichung Industrial Park,

Taichung, 40850, Taiwan, ROC

Date summary prepared: November 24, 2015

510(k) Number: K151656

Proprietary Name: HEARTWAY Power Mobility Scooter, Cutie S17

Common or Usual Name: POWERED SCOOTER

Classification Name Motorized three-wheeled vehicle

(21 CFR 890.3800, Class II, )

Product Code: INI

Company contact person: Mr. TIEN-HSING YANG (Email: [yhead0722@hotmail.com](mailto:yhead0722@hotmail.com))

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

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

Predicate Device: HEARTWAY Medical Products Co., Ltd.

HEARTWAY Lightweight Power Mobility Scooter, S34

(K101142).

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



### Description of the device:

Cutie S17 power scooter is battery powered and configured with four pneumatic wheels, a swivel seat, a turning tiller column, an upper panel control, a main frame, a rear bumper, a front bumper, and an anti-tipper.

S17 power scooter is operated by two pneumatic **rear wheels** as the drive wheels and two pneumatic **front wheels** as the steering wheels, 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 and lighting function. The **main frame** is equipped with a **rear bumper** and a **front bumper** to allow the scooter to sustain an impact without damage to the power scooter safety system.

**Turning tiller column** is equipped with the head light, back mirrors, a swivel seat with the flipping arm-rests, and a lever to move the seat backward and forward. S17 power scooter maximum weight capacity: **300 lbs (135 kgs)**, S17 power scooter maximum speed: **3.6 mph (5.8 kph)**, and main frame is equipped with independent suspension.

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 10 degrees.
- Ground clearance to battery: 3.73"/100 mm
- Curb climbing ability: 3.73"/100 mm



### **Performance Testing:**

- (1) ANSI/ RESNA WC-2, Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters, 2009. (Exclusion of sections 4.2.3.1, 4.2.4, 4.2.5)
- (2) ISO 7176-1 Wheelchairs - Part 1: Determination of static stability, 1999. (Exclusion of sections 9.4, 9.5, 10.4, 10.5, 11, 12.2)
- (3) ISO 7176-2 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs, 2001. (Exclusion of sections 8.5, 8.6, 9.3, 9.4, 9.5, 10.3, 10.4, 10.5)
- (4) ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2012. (Exclusion of sections 7.3, 7.4, 7.5)
- (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 maneuvering 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.

### **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 provided Standard Data Report for 510(k) Forms (FDA Form 3654)).



**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*

Comparison items	Predicate device	Subject device	Safety and effectiveness of subject device compared to the predicate device
<b>Manufacturer</b>	HEARTWAY Medical Products Co., Ltd.		Same manufacturer
<b>Proprietary name</b>	Lightweight Power Mobility Scooter Series	Power Mobility Scooter Series	Heavier weight design
<b>Model</b>	S34	Cutie S17	Different models
<b>510K Number</b>	K101142	K151656	New listing
<b>Common or Usual name</b>	Powered Scooter	Powered Scooter	Same common name
<b>Intended use</b>	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
<b>Footplates</b>	ABS	ABS	Same material
<b>Incline</b>	10 degrees	10 degrees	Same incline angle
<b>Back upholstery</b>	Fabric	Fabric	Same upholstery
<b>Armrest types</b>	Flip-backward	Flip-backward	Same armrest
<b>Wheel Lock</b>	Push-to-Lock	Push-to-Lock	Same wheel lock
<b>Patient contacting material</b>	Seat PVC material Hand grip PVC material Safety belt PVC material	Seat PVC material Hand grip PVC material Safety belt PVC material	Same material
<b>Biocompatibility</b>	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2009	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Same biocompatibility evaluation



## 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



### *Differences*

Comparison items	Predicate device	Subject device	Safety and effectiveness of subject device compared to the predicate device
<b>Electronic controller</b>	Penny & Giles S-Drive	Dynamic Rhino2 120 Amp	Different controllers
<b>Frame</b>			
<b>Type</b>	Fixed	Fixed	Same type
<b>Material</b>	Carbon Steel Pipe	Aluminum Alloy pipe	Different material
<b>Dimensions</b>			
<b>Overall length</b>	39.0" (995 mm )	51.9" (1320mm)	Larger dimensions
<b>Overall width</b>	19.3" (490 mm)	26.3" (670mm )	
<b>Overall height</b>	37.0" (940 mm)	45.6" (1160mm)	
<b>Seat dimension</b>			
<b>Seat width</b>	22.5" (570 mm)	18.1" (460 mm)	Smaller width
<b>Seat height</b>	16" (408 mm)	18.1" (460 mm)	Larger height
<b>Weight limit</b>	220 lbs (100 kgs)	300 lbs (135 kgs)	Heavier user
<b>Suspension</b>	Cross brace	Full	Different suspension
<b>Rear wheels</b>	8" x 3" solid type x 2	11" x 4" pneumatic type x 2	Larger size & different type
<b>Front Casters</b>	8" x 3" solid x 2	11"x3.5" pneumatic x2	Larger size & different type
<b>Turning Radius</b>	37.4" (950 mm )	40.1" (1020 mm )	Larger turning radius
<b>Ground clearance</b>	2.8" (70 mm )	3.93" (100 mm)	Larger ground clearance
<b>Kerb climbing ability</b>	2.0" (50 mm )	3.93" (100 mm)	Larger kerb climbing ability



# 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



## HEARTWAY

<b>Scooter weight</b>	w/ batteries: 96 lbs (43.6 kgs)  w/o batteries: 81 lbs (36.6 kgs)	w/ batteries: 247 lbs (110 kgs)  w/o batteries: 190 lbs (85 kgs)	Heavier scooter weight
<b>Maximum speed</b>	4.8 mph (7.8 kph)	3.6 mph (5.8 kph)	Smaller max speed
<b>Recharger type</b>	24VDC (UL E241359 certified)	24VDC (E201162 certified)	Different models with UL certificates
<b>Model</b>	4C24020A	4C24050A	
<b>Motor</b>	3A, 24V, 270W	10A, 24V, 700W	Larger power motor
<b>Batteries</b>	Two  12Ah 12VDC  6~9 miles (10~15 km)	Two  50Ah 12VDC  21 miles (34 km)	Same quantity
<b>Quantity</b>			Larger capacity
<b>Type</b>			Larger range
<b>Range per full charging</b>			
<b>Warranty</b>	<b>3 years:</b> Main frame <b>1 years:</b> Controller / gear motor / batteries w/o exhaustive and wear parts	<b>2 years:</b> Main frame <b>1.5 years:</b> Controller <b>1 year</b> gear motor w/o exhaustive and wear parts	Shorter period warranty



## COMPARISON DISCUSSION

The intended uses for two devices are the same. Incline capability, footplates, armrest type, wheel lock and the biocompatibility evaluation are the same. The back upholstery material is also the same and passed the resistance ignition test in accordance with ISO 7176-16.

Mainframes of two devices are fixed type, and frame materials of the two devices are different but they both passed the strength and fatigue tests. The weight limit of HEARTWAY Lightweight Power Mobility Scooter, S34 is 220 lbs (100kgs) and the subject device HEARTWAY Power Mobility Scooter Cutie S17 is 300 lbs (135 kgs). In order to load a heavier user, the subject device must be equipped with larger seat height and larger front and rear wheels. In order to have a longer cruise range, the motor power and the battery capability must be larger. The larger seat height can thus load a larger battery volume. The larger front and rear wheels lead to larger turning radius, ground clearance, kerb climbing ability. Finally, larger seat height, larger front and rear wheels, bigger batteries add to a heavier weight of the power scooter. The pneumatic tires and independent full suspension for the subject device can absorb more impact than the solid tires and cross brace suspension for the predicate device, thus leading to more comfort. Under normal driving and maintenance conditions, pneumatic tires have the same safety and effectiveness concerns as the solid tires.

In a word, the subject device has a higher seat due to a heavier user load design and thus possesses a higher center of gravity, which leads to less stable capabilities and more tip over hazard when moving fast. So, the maximum speed of the subject device is limited to smaller value. It is 3.6 mph (5.8 kph) for subject device and 4.8 mph (7.8 kph) for predicate device. This limitation can bring more safety and reduce tip-over hazard. This higher seat difference is equalized by limiting the maximum speed.

The electronic controllers are different, but the subject device met the requirements of the software validation and passed the relevant performance tests of ISO 7176-14:2008. Thus, the subject device doesn't raise any safety and effectiveness concerns.

The chargers are different type. The charger for the subject device is UL-certified. Thus, the subject device doesn't raise any safety and effectiveness concerns.



The larger power capability of battery for the subject device leads to a larger travel range per full charged battery than the predicate device. This difference is related to the safety aspect, but brings more convenience.

The warranty periods are shorter. Even the periods are shorter, the users are required to follow the instructions for use in the owner's manual to drive the scooter. The differences in warranty periods may lead to more consuming money paid by the users, but not related to the safety and effectiveness aspects.

At last, subject devices pass the performance tests according to Safety standards of ISO 7176 series and the EMC test of ANSI / RESNA WC-2, Section 21:2009. The overall performances of the subject devices are ensured.

## CONCLUSIONS

The subject device, HEARTWAY Power Mobility Scooter Cutie S17, 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 subject 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.**