



Food and Drug Administration
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September 29, 2015

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

Re: K150998
Trade/Device Name: HEARTWAY Power Mobility Scooter, Cutie Mini S16
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 13, 2015
Received: August 28, 2015

Dear Dr. 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,

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)

K150998

Device Name

Heartway Power Mobility Scooter, Cutie Mini S16

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)

Michael J. Hoffmann -S

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

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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: September 24, 2015

Device Name:

Proprietary Name: HEARTWAY Power Mobility Scooter, Cutie Mini S16

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)

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Predicate Device 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 Mini S16 is battery operated and configured with two rear pneumatic wheels as the drive wheels and two front pneumatic wheels as the steering wheels. The device uses the upper panel control to control the turning tiller



column mechanism to control the front wheel as the steering directions. 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 to allow the device to sustain an impact without damage to the power scooter safety system and with an independent suspension

- Tuning tiller column is equipped with the head light, back mirrors, and a swivel seat with the flipping arm-rests, and a lever to move the seat backward and forward. Cutie Mini S16 maximum weight capacity is **300 lbs (135 kg)**, and the maximum speed is **3.6 mile/hr (6 km/hr)**

Owing to the feature of the body structure, the two rear wheels can always contact the surface, and the device can drive on the rough surface. But the following surfaces are recommended not to operate on:

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Too steep incline over 6 degrees.
- Turning Radius: 1020 mm / 40.1”
- Ground clearance 90 mm / 3.5”
- Curb climbing ability: 60 mm / 2.4”

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



HEARTWAY MEDICAL PRODUCTS CO.,LTD.

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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 firm
MODEL NO	S34	Cutie Mini S16	Different model
510K NO	K101142	K150998	New listing with prior submissions
Proprietary name	Lightweight Power Mobility Scooter Series	Power Mobility Scooter Series	Heavier weight design
Common or Usual name	Powered Scooter	Powered Scooter	Same name
Regulation Number	21 CFR 890.3800 Motorized Three-Wheeled Vehicle	21 CFR 890.3800 Motorized Three-Wheeled Vehicle	Same regulation number
Product Code	INI	INI	Same code
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 uses



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Footplates	ABS	ABS	Same material
Suspension	Cross brace	Cross brace	Same
Back upholstery	Fabric	Fabric	Same
Armrest types	Flip-backward	Flip-backward	Same
Wheel Lock	Push-to-Lock	Push-to-Lock	Same
Patient contacting material	Seat PVC material Hand grip PVC material Safety belt PVC material	Seat PVC material Hand grip PVC material Safety belt PVC material	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



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Differences:

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE	Safety and effectiveness of subject device compared to the predicate device
Frame Type Material	Fixed Carbon Steel Pipe	Fixed Aluminum Alloy pipe	Same type Lighter material
Dimensions Overall length Overall width Overall height	995 mm / 39.0" 490 mm /19.3" 940 mm / 37.0"	1195 mm / 47.0" 620 mm / 24.4" 1200 mm / 47.2"	Larger dimensions
Seat dimension Seat width Seat height	570 mm /22.5" 408 mm / 16"	570 mm / 22.5" 635 mm / 25"	Same width Larger height
Weight limit	100 kgs / 220 lbs	135 kgs / 300 lbs	Heavier user
Rear wheels	8" x 3" solid x 2	11" x 4" pneumatic x 2	Larger size & different type
Casters	8" x 3" solid x 2	11" x 4" pneumatic x 2	Larger size & different type
Turning Radius	950 mm / 37.4"	1020 mm / 40.1"	Larger radius
Ground clearance	70 mm / 2.8"	90 mm / 3.5"	Larger clearance
Kerb climbing ability	50 mm / 2.0"	60 mm / 2.4"	Larger ability
Scooter Weight	w/ batteries 43.6kgs / 96 lbs w/o batteries 36.6kgs / 81 lbs	w/ batteries 83kgs / 183 lb w/o batteries 60kgs/132 lbs	Heavier weight
Maximum speed	7.8 km/hr (4.875 mile/h)	6.0 km/hr (3.6 mile/h)	Smaller speed
Incline	10 degrees	6 degrees	Safer slope
Electronics	Penny & Giles S-Drive 45A	Penny & Giles S-Drive 70A	Same type with different volume controllers



Recharger Model	24VDC (UL E241359 certified) 4C24020A	24VDC (UL E201162 certified) 4C24050A	Different models with UL certificates
Motor	3A, 24V, 270W	6A, 24V, 400W	Larger power
Batteries Quantity Type	Two 12Ah 12VDC	Two 36Ah 12VDC	Same quantity Larger capacity
Range per full charging	10~15 km / 6~9 miles	30 km / 19 miles	Longer range
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 for two devices are the same. PG S-Drive electric controller, suspension of cross brace, footplates, armrest type, the warranty of the components are the same. The back upholstery material is also the same and passed the resistance ignition test in accordance with ISO 7176-16.

The electronic systems between two devices, for example, the same type of S-Drive with different volume electronic controller, batteries, recharger, and the competent components are from the same suppliers, which were all passed UL certifications. Thus, the same electric safety level for the two devices is assured.

There are safer incline capabilities 6° and 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.

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 safety and effectiveness are ensured. The weight limit of HEARTWAY Lightweight Power Mobility Scooter, S34 is 100 kgs / 220 lbs and the subject device HEARTWAY Power Mobility Scooter Cutie Mini S16 is 135 kgs / 300 lbs. In order to load a heavier user, the subject device must be equipped with larger seat height and larger castors 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 castors and rear wheels lead to larger turning radius, ground clearance, kerb climbing ability. Finally, larger seat height, larger castors and rear wheels, bigger battery add to a heavier weight of the power scooter. The pneumatic tires for the subject device can absorb more impact while driving than the solid tires 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 the above considerations and thus possessing a higher center of weight, which leads to less stable capabilities and more tip over hazard when moving fast. So, the maximum speed of the subject device is reduced to a safety level. It is 6.0 km/h (3.6 mile/h) for subject device and 7.8 km/h (4.875 mile/h) for predicate device. This limitation can bring more safety level and reduce tip over hazard. Thus, the main difference between two devices is the seat height dimension only. This main difference is equalized by limiting the maximum speed.

At last, two devices pass the performance tests in accordance with ISO 7176 series standards and the ANSI / RESNA WC-2, Section 21 for the EMC test. The overall performances of the two devices are substantially equivalent.

CONCLUSIONS

The subject device, HEARTWAY Power Mobility Scooter, Cutie Mini S16, 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.