DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 29, 2014

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

Re: K132855
Trade/Device Name: HEARTWAY Power Mobility Scooter, S15
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: July 25, 2014
Received: July 30, 2014

Dear Dr. 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" (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,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
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 on last page.*

510(k) Number *(if known)*
K132855

Device Name
HEARTWAY Power Mobility Scooter, S15

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a seated 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)*

Felipe Aguel -S Date: 2014.08.29 09:53:38 -04'00'

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HEARTWAY

# " 510(k) SUMMARY "

# K132855

Submitter's Name: ***HEARTWAY Medical Products Co., Ltd.***
No.6, Road 25, Taichung Industrial Park, Taichung, 40850, Taiwan, ROC

Date summary prepared: August 21, 2014

Device Name:

Proprietary Name: HEARTWAY Power Mobility Scooter, S15

Common or Usual Name: POWERED SCOOTER

Classification Name: MOTORIZED 4-WHEELED VEHICLE, Class II, 21 CFR 890.3800

Product Code: INI

Company contact Henry Wu (henry@heartway.com.tw)

Official Correspondent Dr. Jen, Ke-Min

Tel: +886-4-23580357 Fax: +886-3-5209783

Email:ceirs.jen@msa.hinet.net

Indications for Use:

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

Description of the device:

The HEARTWAY Power Mobility Scooter, S15 is an indoor / outdoor powered scooter that is battery operated. It has a base with four-wheeled with a seat, and armrests. The movement of the powered scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an external battery recharger.

Performance Testing:

1) EMC Report ANSI / RESNA WC/Vol.2: 2009, CISPR 11: 2004+A2:2006, EN61000-4-2: 2008, IEC61000-4-3: 2006, IEC61000-4-8: 2001 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods).
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.

Device major components description

The maximum weight bearing capacity of the device is 160 kgs / 350 lbs.

The feature of the body structure, the rear two wheels can always contact the surface, and the vehicle can operate on the rough surface. We provide the components and assembling drawing in the User's Manual. 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 10 degrees.
- Turning Radius 1,280 mm / 50.4”
- Ground clearance 80 mm / 3.15”
- Kerb climbing ability 75 mm / 2.9”

Legally marketed device for substantial equivalence comparison:

Predicate Device: HEARTWAY Power Mobility Scooter, S12 (K092650)

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HEARTWAY

**Comparison Table:**

| Comparison items | PREDICATE DEVICE | SUBJECT DEVICE | Safety and effectiveness of subject device compared to the predicate. |
|---|---|---|---|
| **BRAND NAME** | HEARTWAY | | Same |
| **MANUFACTURER** | HEARTWAY Medical Products Co., Ltd. | | Same |
| **SERIES** | Power Mobility Scooter Series | | Same |
| **MODEL NO** | S12 | S15 | Same |
| **510K NO** | K092650 | K132855 | Same |
| **INTENDED USE** | The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. | Same | Same |
| **Frame** | Folded | Same | Same |
| **Frame material** | Carbon Steel Pipe | Same | Same |
| **Overall dimension** | | | |
| **Overall length** | 1400 mm / 55.1” | Same | Same |
| **Overall width** | 700 mm / 27.5” | Same | Same |
| **Overall height** | 1360 mm / 53.5” | Same | Same |

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| | | | |
|---|---|---|---|
| **Seat Width**<br>**Seat Height** | 620 mm / 24.5”<br>820 mm / 32.25” | Same<br>Same | Same<br>Same |
| **Weight limit** | 160 kgs / 352 lbs | Same | Same |
| **Maximum speed** | 9.6 km/h ( 6.0 mile/h ) | Same | Same |
| **Batteries**<br>**Quantity**<br>**Type**<br>**Range per charge** | Two<br>50 Ah 12VDC<br>40km / 25 miles | Same | Same |
| **Motor** | 24V DC, 700 W | Same | Same |
| **Rear wheels** | 13” x 3.5” solid x 2 | Same | Same |
| **Casters** | 13” x 5.0” solid x 2 | Same | Same |
| **Footplates** | ABS | Same | Same |
| **Suspension** | Cross brace | Same | Same |
| **Incline** | 10 degrees | Same | Same |
| **Turning Radius** | 1,280 mm / 50.4” | Same | Same |
| **Ground clearance** | 75 mm / 2.9” | Same | Same |
| **Kerb climbing ability** | 80 mm / 3.1” | Same | Same |
| **Back upholstery** | Fabric | Same | Same |
| **Armrest types** | Flip-backward | Same | Same |
| **Wheel Lock** | Push-to-Lock | Same | Same |

| | | | |
|---|---|---|---|
| **Warranty** | **3 years**: Main frame<br>**1 years**: Controller / gear motor / batteries w/o exhaustive and wear parts | Same | Same |
| **Patient contacting materials** | 1.Seat PVC material<br>2.Hand grip PVC material<br>3.Seat belt PVC material | Same | Same |
| **Biocompatibility** | ISO 10993-1<br>ISO 10993-5 | Same | Same |

*Differences:*

| ITEMS | PREDICATE DEVICE | SUBJECT DEVICE | **Safety and effectiveness of subject device compared to the predicate.** |
|---|---|---|---|
| **Wheelchair Weight** | w/ batteries 132 kgs(291lbs)<br>w/o batteries: 94 kgs (207 lbs) | w/ batteries 136kgs(299 lbs)<br>w/o batteries 98kgs (216 lbs) | 4 kgs difference is about 3.03% of the predicate weight, not to change the center of weight much. |
| **Electronics Controller** | RHINO<br>DS112K Drive | RHINO<br>DS120 Drive | Both controllers are TUV certified. |
| **Recharger model** | 24VDC<br>4C24080A<br>(UL E201162 certified) | 24VDC<br>4F24050<br>(UL E241359 certified) | Both rechargers are UL certified. |

**Summary for substantial equivalence comparison:**

The intended use between the two devices is the same. Mainframes of two devices are folded. All materials of the two devices meet the strength and fatigue tests and they use the same material. The same size of wheels, the weight limit, cruising range, maximum speed, incline capabilities, suspension of cross brace, footplates, armrest type, the

warranty of the components, and the relevant specifications for ground clearance and curb climbing ability are all the same. The back upholstery material is also the same fabric and passed the resistance ignition test in accordance with ISO 7176-16.

The main differences among the two devices are the different models of the electronics controller and battery rechargers. But they are all certified ones. Thus, these differences only lead to the different wheelchair weights. The differences of weight between two devices are so small, only 3.03% of the predicate wheelchair weight. The 3.03% of the different weight does not lead to the large change of the centers of weight. The centers of weight are almost at the same point, thus the safety and effectiveness aspects are the same.

Two devices also completed the performance tests in accordance with ISO 7176 series standards and the ANSI / RESNA WC 2, Section 21 for the EMC test. The two devices are substantially equivalent.

**Conclusion:**

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 devices.