JUL 15 2014

HEARTWAY MEDICAL PRODUCTS CO.,LTD.
NO.6, ROAD 25, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN R.O.C. 408
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" 510(k) SUMMARY "

K132856

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

Date summary prepared: July 15, 2014

Device Name:

Proprietary Name:	HEARTWAY Power Wheelchair, P25
Common or Usual Name:	POWERED WHEELCHAIR
Classification Name:	POWERED WHEELCHAIR, Class II, 21 CFR 890.3860
Product Code:	ITI

Name of Contact Person: 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 Wheelchair, P25 is an indoor / outdoor power chair that is battery operated. It has a base with four-wheeled with a seat, and armrests. The movement of the power chair 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 charger.

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, 2003.
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, 1992.
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 120 kgs / 265 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 650 mm / 25.6"
- Ground clearance 80 mm / 3.2"
- Curb climbing ability 75 mm / 3.0"

Compare to the legally marketed device for substantial equivalence:

Predicate Device: HEARTWAY Power Chair, P23 (K100327)

Summary for substantial equivalence comparison:

The indications for use between the two devices are the same. Mainframes of two devices are folded and they use the same material. The mainframe materials of the two devices all meet the strength and fatigue tests. The incline capabilities, cross brace suspension, footplates, armrest type, and the warranty are all the same. The back upholstery material is also made of the same fabric and passes the ignition-resistance test in accordance with ISO 7176-16.

Specifically, the electronic systems for two devices are the same controller, i.e., P & G VR2, and are from the same suppliers. The electronic controller, batteries, recharger, and the competent switches and switching power supplies all pass the UL certification. Thus the same safety and effectiveness levels for the two devices are assured.

The main differences for the two devices are overall dimensions. Therefore, the weight limit, cruising range, maximum speed, wheelchair weight, the sizes of wheels and seat, and the relevant specifications for ground clearance and curb climbing ability are different. But two devices all meet the ISO 7176 series standards requirements. Thus for the real-life use instead of different dimensional specifications, the two devices are substantially equivalent.

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HEARTWAY

Comparison Table

Similarities:

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
BRAND NAME	HEARTWAY	
MANUFACTURER	HEARTWAY Medical Products Co., Ltd.	
SERIES	Power Wheelchair System Series	
MODEL NO	P23	P25
510K NO	K100327	K132856
INTENDED USE	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same
Frame	Folded	Same
Electronics	P & G, VR2 controller	Same
Suspension	Cross brace	Same
Footplates	ABS	Same
Incline	10 degrees	Same
Back Upholstery	Fabric	Same
Armrest Types	Flip-backward	Same
Recharger	24VDC (UL 1310 certified)	Same
Wheel Lock	Push-to-Lock	Same
Warranty	**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
Overall Dimension		
Overall length	1100 mm / 43.3"	830 mm / 32.7"
Overall width	660 mm / 26.0"	650 mm / 25.6"
Overall height	1100 mm / 43.3"	1060 mm / 41.7"
Weight Limit	135 kgs / 300 lbs	120 kgs / 265 lbs
Maximum Speed	6.0 km/hr (3.8mile/h)	9.6 km/hr (6.0mile/h)
Batteries		
Quantity	Two	Two
Type	34Ah 12VDC	50Ah 12VDC
Range per charge	26~30km / 18 miles	35km / 22 miles
Rear Wheels	10" x 3.3" solid x 2	14" x 3.0" solid x 2
Casters	6.0" x 2" solid x 2	10" x 3.3" solid x 2
Seat Size		
Width	66 cm / 26.0"	48 cm / 18.9"
Length	85 cm / 33.5"	44 cm / 17.3"
Height	30 cm / 11.8"	53 cm / 20.9"
Turning Radius	550 mm / 21.7"	650 mm / 25.6"
Ground Clearance	75 mm / 3.0"	80 mm / 3.2"
Curb Climbing Ability	60 mm / 2.4"	75 mm / 3.0"
Wheelchair Weight	w/i batterics 85kgs / 187 lbs w/o batteries 60kgs / 132 lbs	w/i batteries 125kgs / 276 lbs w/o batteries 75kgs / 165 lbs

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

July 15, 2014

HEARTWAY Medical Products Co., Ltd.
c/o Dr. Jen, Ke-Min
No. 6 Road 25, Taichung Industrial Park
Taichung, 40850
Taiwan, ROC

Re: K132856
Trade/Device Name: HEARTWAY Power Wheelchair, P25
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 5, 2014
Received: June 12, 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, 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132856

Device Name
HEARTWAY Power Wheelchair, P25

Indications for Use *(Describe)*
This 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: 2014.07.15 17:47:42 -04'00'

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.

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