"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:
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
8) ISO 7176-7 Wheelchairs - Part 7: Determination of seating dimensions - Definitions
9) ISO 7176-8 Wheelchairs - Part 8: Static, impact and fatigue strength for manual
11) ISO 7176-10 Wheelchairs - Part 10: Determination of obstacle-climbing ability of
electrically powered wheelchairs, 2008.
13) ISO 7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test
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.
## Comparison Table

<table>
<thead>
<tr>
<th>ITEMS</th>
<th>PREDICATE DEVICE</th>
<th>SUBJECT DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAND NAME</td>
<td>HEARTWAY</td>
<td>HEARTWAY</td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>HEARTWAY Medical Products Co., Ltd.</td>
<td>HEARTWAY Medical Products Co., Ltd.</td>
</tr>
<tr>
<td>SERIES</td>
<td>Power Wheelchair System Series</td>
<td>Power Wheelchair System Series</td>
</tr>
<tr>
<td>MODEL NO</td>
<td>P23</td>
<td>P25</td>
</tr>
<tr>
<td>510K NO</td>
<td>K100327</td>
<td>K132856</td>
</tr>
<tr>
<td>INTENDED USE</td>
<td>The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.</td>
<td>Same</td>
</tr>
<tr>
<td>Frame</td>
<td>Folded</td>
<td>Same</td>
</tr>
<tr>
<td>Electronics</td>
<td>P &amp; G. VR2 controller</td>
<td>Same</td>
</tr>
<tr>
<td>Suspension</td>
<td>Cross brace</td>
<td>Same</td>
</tr>
<tr>
<td>Footplates</td>
<td>ABS</td>
<td>Same</td>
</tr>
<tr>
<td>Incline</td>
<td>10 degrees</td>
<td>Same</td>
</tr>
<tr>
<td>Back Upholstery</td>
<td>Fabric</td>
<td>Same</td>
</tr>
<tr>
<td>Armrest Types</td>
<td>Flip-backward</td>
<td>Same</td>
</tr>
<tr>
<td>Recharger</td>
<td>24VDC (UL 1310 certified)</td>
<td>Same</td>
</tr>
<tr>
<td>Wheel Lock</td>
<td>Push-to-Lock</td>
<td>Same</td>
</tr>
<tr>
<td>Warranty</td>
<td>3 years: Main frame 1 years: Controller / gear motor / batteries w/o exhaustive and wear parts</td>
<td>Same</td>
</tr>
</tbody>
</table>
### Differences:

<table>
<thead>
<tr>
<th>ITEMS</th>
<th>PREDICATE DEVICE</th>
<th>SUBJECT DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Dimension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall length</td>
<td>1100 mm / 43.3”</td>
<td>830 mm / 32.7”</td>
</tr>
<tr>
<td>Overall width</td>
<td>660 mm / 26.0”</td>
<td>650 mm / 25.6”</td>
</tr>
<tr>
<td>Overall height</td>
<td>1100 mm / 43.3”</td>
<td>1060 mm / 41.7”</td>
</tr>
<tr>
<td>Weight Limit</td>
<td>135 kgs / 300 lbs</td>
<td>120 kgs / 265 lbs</td>
</tr>
<tr>
<td>Maximum Speed</td>
<td>6.0 km/hr (3.8 mile/h)</td>
<td>9.6 km/hr (6.0 mile/h)</td>
</tr>
<tr>
<td>Batteries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quantity</td>
<td>Two</td>
<td>Two</td>
</tr>
<tr>
<td>Type</td>
<td>34Ah 12VDC</td>
<td>50Ah 12VDC</td>
</tr>
<tr>
<td>Range per charge</td>
<td>26–30km / 18 miles</td>
<td>35km / 22 miles</td>
</tr>
<tr>
<td>Rear Wheels</td>
<td>10” x 3.3” solid x 2</td>
<td>14” x 3.0” solid x 2</td>
</tr>
<tr>
<td>Casters</td>
<td>6.0” x 2” solid x 2</td>
<td>10” x 3.3” solid x 2</td>
</tr>
<tr>
<td>Seat Size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Width</td>
<td>66 cm / 26.0”</td>
<td>48 cm / 18.9”</td>
</tr>
<tr>
<td>Length</td>
<td>85 cm / 33.5”</td>
<td>44 cm / 17.3”</td>
</tr>
<tr>
<td>Height</td>
<td>30 cm / 11.8”</td>
<td>53 cm / 20.9”</td>
</tr>
<tr>
<td>Turning Radius</td>
<td>550 mm / 21.7”</td>
<td>650 mm / 25.6”</td>
</tr>
<tr>
<td>Ground Clearance</td>
<td>75 mm / 3.0”</td>
<td>80 mm / 3.2”</td>
</tr>
<tr>
<td>Curb Climbing Ability</td>
<td>60 mm / 2.4”</td>
<td>75 mm / 3.0”</td>
</tr>
<tr>
<td>Wheelchair Weight</td>
<td>w/ batteries 85kgs / 187 lbs</td>
<td>w/ batteries 125kgs / 276 lbs</td>
</tr>
<tr>
<td></td>
<td>w/o batteries 60kgs / 132 lbs</td>
<td>w/o batteries 75kgs / 165 lbs</td>
</tr>
</tbody>
</table>
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: H11  
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” (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,

Felipe Aguel -S
Carlos L. Peña, PhD, MS
for Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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'

FORM FDA 3881 (9/13) Page 1 of 2
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

*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.*