

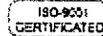
K092154

SEP 21 2009



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

“ 510(k) SUMMARY ”

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

No.6, Road 25, Taichung Industrial Park, Taichung, 408, Taiwan, ROC

Date summary prepared:

July 1, 2009

Device Name:

- Proprietary Name: HEARTWAY Power Mobility Scooter, S9
- Common or Usual Name: POWERED SCOOTER
- Classification Name: MOTORIZED 4-WHEELED VEHICLE, Class II,
21 CFR 890.3800
- Product Code: INI

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, S9 is an indoor / outdoor electric scooter that is battery operated. It has a base with four-wheeled with a seat, armrests, and a front basket. The movement of the 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 onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

HEARTWAY Power Mobility Scooter, PF6 (K072104)



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Summary for substantial equivalence comparison:

According to the above table that the intended use between the two devices is the same. Mainframes materials of the two devices are fixed, and all meet the strength and fatigue tests and they use the same material aspects. Moreover, the weight limit, maximum speed, cruising range, suspension of cross brace, footplates, and armrest type are all the same. The back upholstery material is also the same fabric and passed the resistance ignition test.

Especially the electronic systems between two devices are the same suppliers, and all passed by the UL certificated, for instance the electronic controller, batteries, battery charge, and the competent switches and switching power supplies. Thus the same safety level for the two devices is assured.

The maximum slope for the two devices is difference. This means the new device is 12°, the predicate device is 10°. Certainly the real incline depends on the practical environments, i.e., weight, surface, and temperature. For the real life use, the two devices are substantially equivalent.

The main differences for the two devices are overall appearance, wheels size, weights, and the warranty are difference between the two devices. The safety levels of the two devices are the same and the overall appearance differences are not safety aspect. They are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 21 2009

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

Heartway Medical Products Co., LTD
% Chinese-European Industrial Research Society
Ke-Min Jen
No., 58, Fu-Chiun Street
Hsin-Chu City
China (Taiwan) 408

Re: K092154

Trade/Device Name: HEARTWAY Power Mobility Scooter, S9
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: July 1, 2009
Received: July 16, 2009

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.

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/> 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style and is positioned above a horizontal line that extends to the left.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K

Device Name: HEARTWAY Power Mobility Scooter, S9

Indications for Use:

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

Prescription Use _____

AND/OR

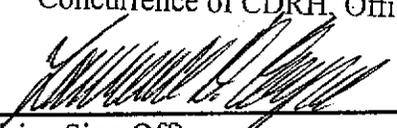
Over-The-Counter Use √

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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