K061694

MEDCARE MANUFACTURING INC.

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" 510(k) SUMMARY "

JUL - 5 2006

Submitter's Name: *MEDCARE MANUFACTURING INC.*
No.351, Chungcheng Rd., Sec. 2, Changhua, 50041, Taiwan, R.O.C.

Date summary prepared: June 10, 2006

Device Name:

Proprietary Name:	MEDCARE Mechanical Wheelchair, MC-281S and MC-200S
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Mechanical Wheelchair, Class I, 21 CFR 890.3850

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 WH Convertible Lightweight Wheelchair MC-281S and MC-200S is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. Back upholstery material is also the same resistance-ignitability fabric.

Performance Testing:

MC-281S and MC-200S are Foldable Wheelchair meet the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair Standards.

Legally marketed device for substantial equivalence comparison:

WH Convertible Lightweight Wheelchair, WHL100 (K060251)

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Summary for substantial equivalence comparison:

The intended use of the two devices is the same, and mainframes of two devices are the same foldable. The overall dimensions are similar. Back upholstery material is also the same resistance -ignitability fabric. **The major differences existing are the overall dimension, and the size of tires are differences between the two devices. Especially, the subject device MC-281S has the head cushion.** The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

The weight limit of the subject device is 100 kgs / 220 lbs and the predicate device is 250 lbs. The seat heights between the new device and the predicate device have small difference, not leading to any safety hazard. The hanger and rear axle designs are same. The weight of the new device is heavier and the user can feel more stable to transport it. At last the optional accessories for the two devices are same, and the users have the same status to choose the needed accessories to accommodate their needs.

Thus the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDCARE MANUFACTURING INC.
% ROC CHINESE-EUROPEAN INDUSTRIAL
RESEARCH SOCIETY
Dr. Ke-Min Jen
No. 58 Fu-Chiun St.
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JUL - 5 2006

Re: K061694
Trade/Device Name: MEDCARE Mechanical Wheelchair, MC 281S, MC-200S
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulation Class: I
Product Code: IOR
Dated: June 10, 2006
Received: June 15, 2006

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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

Enclosure

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Indications for Use

510 (K) Number (If Known): K 061694

Device Name: *MEDCARE Mechanical Wheelchair, MC-281S, MC-200S*

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 General, Restorative, and Neurological Devices

510(k) Number K061694