K062311

OCT - 4 2006

" 510(k) SUMMARY "

Submitter's Name: KARMA Medical Products Co., Ltd.
No. 2363, Sec.2, Da-Shiue Road, Min-Hsiung Shiang, Chia-Yi Hsien, 62144, Taiwan, R.O.C.

Date summary prepared: August 4, 2006

Device Name:

Proprietary Name:	KARMA Manual Wheelchair, Budget 800
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 KARMA Manual Wheelchair, Budget 800 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:

The KARMA Manual Wheelchair, Budget 800 is 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)

Comparison Table

ITEMS	SUBJECT DEVICE	PREDICATE DEVICE
BRAND NAME	*KARMA*	*WH*
MANUFACTURER	*KARMA Medical Products Co., Ltd.*	*Well Home Health Products Co.*
MODEL NO	**Budget 800**	**WML100**
510K NO	***K062311***	***K060251***
INTENDED USE	SAME	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*
FRAME **Width** **Cross brace** **Depth** **Seat** **Backrest height** **Reclining backrest** **Seat sling** **Frame colors**	 610 mm SAME 1080 mm width: 407mm / 458 mm length: 432mm SAME SAME SAME SAME	 21" (534mm) **YES** 15.7"(400mm) width: 18" (458mm) depth: 16" (406mm) adjustable fixed padded nylon blue, black
ARMREST **Arm pad** **Flip back** **Height-adjustable**	SAME	 Padded YES, non-detachable NO
HANGERS **Swing-away** **Elevating leg rest** **Articulating leg rest** **Footplate style** **Heel loop** **Footrest angle**	 **SAME** **SAME** **SAME** Stainless SAME **30^0**	 **NO** **NO** **NO** Nylon fiber(one-piece style) NO **70^0**
REAR AXLE **Offset axle** **Quick-release axle**	SAME	 YES YES

ITEMS	SUBJECT DEVICE	PREDICATE DEVICE
MODEL NO	**Budget 800**	**WML100**
REAR WHEEL **Size** **Tire type** **Handrim material**	24"	convert 12" or 24"
CASTERS **Size** **Tire type**	8" Solid	7" Solid
WHEEL LOCK	SAME	Pull-to-Lock
WEIGHT CAPACITY	SAME	250 lbs / 115 kg
WEIGHT OF CHAIR	14.44 kg or 14.65 kg	15 kg (33 lb)
WARRANTY	5 years on frame	6 years on frame
OPTIONAL ACCESSORIES **Anti-tipper** **Rear stepper** **Fold down push handle**	YES YES YES	YES YES YES

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.** 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 and the predicate device are also 115 kgs. 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 light and portable weight of the new device is similar to the predicate device and the user can feel more convenient 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

OCT - 4 2006

Karma Medical Products Co., Ltd.
% Dr. Jen Ke-Min
No. 2363, Sec.2, Da-Shiue Road
Min-Hsiung Shiang
Chia-Yi Hsien 62144, Taiwan, R.O.C

Re: K062311
Trade/Device Name: KARMA Manual Wheelchair, Budget 800
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 23, 2006
Received: September 27, 2006

Dear Dr. 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.

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,

Barbara Brehm

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

Enclosure

Indications for Use

510 (K) Number (If Known): K062311

Device Name: *KARMA Manual Wheelchair, Budget 800*

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)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062160