K052559

SEP 26 2005

WU'S TECH CO., LTD.

NO. 225, YUAN-PIER ST., HSIN CHU CITY, CHINA (TAIWAN)
TEL: 886-3-5382105 FAX: 886-3-5382191
Homepage: www.wustech.com.tw Email: wustis@ms45.hinet.net

" 510(k) SUMMARY "

Submitter's Name: ***WU'S TECH CO., LTD.***
NO. 225, YUAN-PIER ST., HSIN CHU CITY, CHINA (TAIWAN)

Date summary prepared: September 6, 2005

Device Name:

Proprietary Name:	WU'S POWERED WHEELCHAIR, **MAMBO 2**
Common or Usual Name:	POWERED WHEELCHAIR
Classification Name:	POWERED WHEELCHAIR, Class II, 21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricte to a seated position.

Description of the device:

The WU'S Powered Wheelchair **MAMBO 2** is an indoor / outdoor electric scoot 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:

WU'S POWERED WHEELCHAIR, **MAMBO 3** (K030707)

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages.)

We can know from the above table that the intended use between the two devices is the same. Mainframes of two devices are foldable. Mainframes materials of the two devices all meet the strength and fatigue tests and they are similar for the material aspects. The overall dimensions are similar. The two devices used the same type of armrest and the same weight limit. Back upholstery material is also the same fabric. Besides the recharger, batteries, and these critical electrical components are also certified by UL. For the operator's safety aspect they are substantially equivalent.

The maximum speed for the new device is 3.5 mph and 4.0 mph for the predicate device. Lower speed means the new device shall more easily to meet the relevant requirements for the braking time, distance, and dynamic stability for safety considerations.

The major difference existing for new device is more agile and easy to fold for storage or transportation and the predicate device is for general use. The control systems for the two devices are different. It is Dynamic DL for the predicate device and Penny & Giles for the new device. Two of the control systems are all FDA-clearance. The safety and performance functions of two systems are assured and validated. They are substantially equivalent. Maximum range per charge is 16 km for the new device, and 40 km for the predicate device. Certainly the real range depends on the practical environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use the same technological aspects and only minor dimensions and material differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

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Summary for substantial equivalence comparison:

The intended use between the two devices is the same. Mainframes materials of the two devices all meet the strength and fatigue tests and they are similar for the material aspects. The overall dimensions are similar. The two devices used the same type of armrest and the same weight limit. Back upholstery material is also the same fabric. Besides the recharger, batteries, and these critical electrical components are also certified by UL. For the operator's safety aspect they are substantially equivalent.

The major difference existing for new device is more agile and easy to fold for storage or transportation and the predicate device is for general use. The differences existing are control system, the size of seat, maximum speed, cruising range, and the incline degrees are differences between the two devices. The overall appearance differences are not safety aspect. 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

SEP 26 2005

ROC Chinese-European Industrial Research Society
c/o Dr. Jen Ke-Min
Wu's Tech Co., LTD
No. 58, Fu-Chiun Street
Hsin-Chu City, China (Taiwan) 300

Re: K052559
Trade/Device Name: WU'S POWERED WHEELCHAIR, MAMBO 2
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 6, 2005
Received: September 16, 2005

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.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K052559

Device Name: *WU'S POWERED WHEELCHAIR, **MAMBO 2***

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 NEEDI

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052559

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