K042748

NOV 1 2 2004

Genemax Medical Products Industry Corp.
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" 510(k) SUMMARY "

Submitter's Name: ***Genemax Medical Products Industry Corp.***
No. 86, Lane 226, Tai-Ming Rd., Wu-Jih Taichung, 414, Taiwan, R.O.C.

Date summary prepared: September 28, 2004

Device Name:

Proprietary Name:	Genemax Power Wheelchair, PW3
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 Genemax Power Wheelchair, PW3 is an indoor / outdoor Powered Wheelchai that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair 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, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

TEH LIN Power Wheelchair, TL-320 **(K022697)**

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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. The **batteries** used are the same supplier and similar U1 type. The **control** systems for the two devices are used from same brand: **Penny & Giles**. The **recharge** for the two devices are also used the same supplier, and the chargers are also certified by UL. Besides, the **foldable frame**, removable **armrest type**, same **cruising range,** same **footplates,** same **incline,** and **back upholstery** are the same material that also be passed the resistance ignition test by SGS.

The weight capabilities for the two devices are different, and there is 22.1 pounds difference, between 264.6 pounds and 242.5 pounds. This means the new device can bear more weight than the predicate device. The safety levels of the two devices are the same when operating the devices on the same 12 degrees inclines. They are substantially equivalent.

The maximum speed for the new device is 5 mph and 2.62 mph for the predicate device. Higher speed means the new device shall meet relevant requirements for the braking time, distance, and dynamic stability for safety considerations. The different maximum speeds do not lead any safety considerations and they are substantially equivalent in this aspect.

To sum up the mainly different of the two devices are only appearance dimensions, i.e., the overall dimensions, the size of wheels, seat dimensions, weight limit, and maximum speed. For the regular operator, these differences for the two devices do not lead to any performance differences, and 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2004

Genemax Medical Products Industry Corp.
C/o Dr. Jen Ke-Min
Roc Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K042748
Trade/Device Name: GENEMAX Power Wheelchair, PW3
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 29, 2004
Received: October 4, 2004

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

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
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): **K042748**

Device Name: *GENEMAX Power Wheelchair, PW3*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted t
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)

for Mark A. Millman

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

510(k) Number K042748