



ISO 9000

K051482 JUN 29 2005 1/2  
進賢實業有限公司  
JAN MAO INDUSTRIES CO., LTD.

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Wen-Shan Dist., Taipei, Taiwan, R. O. C.  
TEL : 886-2-2930-0381 FAX : 886-2-2937-0459  
E-mail Address : Jewel88@ms77.hinet.net

**“ 510(k) SUMMARY ”**

Submitter's Name: *JAN MAO INDUSTRIES CO., LTD.*  
*No.181, Chu Liao Road, Ta Su Hsiang, Kao Hsiung*  
*Hsian, TAIWAN, 840, ROC*

Date summary prepared: May 27, 2005

Device Name:

Proprietary Name: JAN MAO,  
Wheelchair, JMC612-F18EPP  
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 JAN MAO Wheelchair, JMC612-F18EPP 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. The device uses a standard sling type back and seat, the upholstery fabric meets the California Technical Bulletin CAL 117 standard for flame retardant.

Performance Testing:

JAN MAO Wheelchair, JMC612-F18EPP meets the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair Standards.

Legally marketed device for substantial equivalence comparison:

AVANTICARE Mechanical Wheelchair, MR-9000 ( K050708 )

K051482

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ISO 9002

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Summary for substantial equivalence comparison:

The new device and the predicate device have the same intended use. Mainframes of two devices are foldable. The overall dimensions are similar and same weight capacity. Back upholstery material is also the same resistance -ignitability fabric and also meets the California Technical Bulletin CAL 117 standard for flame retardant. **The major differences existing are the overall dimension. Besides, the predicate device is fixed frame and the new device is removable desk-length armrest and swing-away detachable elevating footrest.** The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate device.



JUN 29 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Jan Mao Industries Company, Ltd.  
C/o Dr. Ke-Min Jen  
ROC Chinese-European Industrial Research Society  
No. 58, Fu-Chiun Street  
Hsin-Chu City, China (Taiwan) 300

Re: K051482

Trade/Device Name: JAN MAO, Wheelchair JMC612-F18EPP  
Regulation Number: 21 CFR 890.3850  
Regulation Name: Mechanical wheelchair  
Regulatory Class: I  
Product Code: IOR  
Dated: May 27, 2005  
Received: June 3, 2005

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.

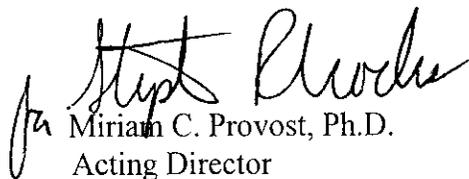
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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 "Miriam C. Provost". The signature is written in a cursive style with a large initial "M".

Miriam C. Provost, Ph.D.  
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 ):     K    

Device Name: JAN MAO, Wheelchair JMC612-F18EPP

Indications for Use:

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

Prescription Use \_\_\_\_\_

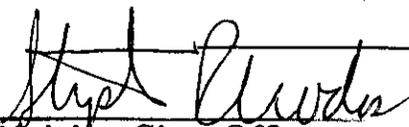
AND/OR

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**

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