K041814

510(K)Summary

JUL 2 0 2004

Submitter's Name: **Foshan Dongfang Medical Equipment Manufactory (LTD.)**

Address: 2 Baohua Industrial Park Ave. Guilan Rd. Nanhai District Foshan City, Guangdong Province, China ,528252

Telephone: 86 -757-6299415

Fax: 86-757-6232649

Contact: Mr. Pang Jianxun , General Manager

Date Prepared:

1. **Device Name:** **FS Wheelchair**

3. **Classification:** **FS Wheelchair** is classified under Mechanical Wheelchair, which has been classified as a Class I device, in accordance to 21 code of Federal Regulations 890.3850

4. Predicate Device: Foshan Machinery & Equipment Import & Export Co. Series Wheel Chair (manual, not electrical)

K992884

5. Device Description:

Foshan Wheelchair is a self-propelled, folding frame, mechanical wheelchair consisting of components typical of most manual wheelchairs. It has large rear wheels with push rims for self-propulsion and small front pivoting casters for turning and stability. It is a lightweight, user adaptable, everyday chair for use both indoors and outdoors.

6. Intended Use

The intended used Foshan Wheelchair is to provide mobility to persons with physical limitations limited to a sitting position.

7. Substantial Equivalence

The Foshan Wheelchair is substantially equivalent to the listed predicate devices in its specifications, performance and use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2004

Foshan Dongfang Medical Equipment Manufactory
C/o Mr. Tamas Borsai
TUV Rheinland of North America, Inc.
12 Commerce Road
Newtown, Connecticut 06470

Re: K041814
Trade/Device Name: FS-Series Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: June 28, 2004
Received: July 6, 2004

Dear Mr. Borsai:

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 (301) 594-4659. 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): Under application

Device Name: FS-Series Wheelchair

Indications For Use:

The FS-series Wheelchair is manually operated mechanical wheelchair, the FS-series Wheelchair provides enhanced mobility to physically challenged persons limited 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)

for Mark N Milhous

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

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