K070501

# Shanghai Ruike Sports Goods CO., LTD.

No. 689, Xinhu Road, Shanghai, China TEL: +86-21-66350714 FAX: +86-21-66351873

# 510(k) Summary

MAR 2 2 2007

**Device**

Trade name: **Ruike 3421 powered wheelchair**

Common name: **Powered wheelchair**

Classification name: **Powered wheelchair**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3860**

Product Code: **ITI**

Classification: **Class II**

**Predicate devices**

**CWD01 (K062888) / EMG Technology Co. Ltd.**

**Intend use of device**

**Ruike 3421** powered wheelchair is intended for an indoor/outdoor power wheelchair that provides transportation for disabled or elderly persons limited to a seated position.

**Device description:**

The **Ruike 3421** powered wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The design of this wheelchair is basically similar to other powered wheelchairs that are already on the market. But the **Ruike 3421** is kind oh a new class of lightweight powered wheelchair. By providing a powered wheelchair that breaks down into two manageable components (seat frame, body frame with motors and battery pack), a user can have a more practical alternative when traveling long distances by bus, train, etc.

**Substantial equivalence:**

The **Ruike 3421 powered wheelchair** is substantially equivalent to the **CWD01 (K062888)** manufactured by **EMG Technology Co. Ltd..**

There are minor differences in performance specifications of the powered wheelchairs, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **Shanghai Ruike Sports Goods CO., LTD.** believes that the **Ruike 3421** powered wheelchair is substantially equivalent to legally marketed devices currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shanghai Ruike Sports Goods Co., Ltd.
% Ms. Junnata Chang
14 F-2, No. 1, Lane 25, Zhuangjing Road
Banqiao, Taipei County, Taiwan (China)

MAR 2 2 2007

Re: K070501
Trade/Device Name: Ruike 3421 powered wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 12, 2007
Received: February 21, 2007

Dear Ms. Chang:

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,

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

Enclosure

**3. Device descriptive information**

**3.1 Statement of indication for use**

# Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **Ruike 3421**

Indications for Use:

The **Ruike 3421** powered wheelchair is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

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

510(k) Number K070521

*(Posted November 13, 2003)*