WU'S TECH CO., LTD. K091212
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

MAY 27 2009

" 510(k) SUMMARY "

Submitter's Name: ***WU'S TECH CO., LTD.***
NO. 225, YUAN-PIER ST., HSIN CHU CITY, 30093, CHINA (TAIWAN)

Date summary prepared: April 17, 2009

Device Name:

Proprietary Name: WU'S 3-WHEELED ELECTRICAL SCOOTER, **WT-T3H**
Common or Usual Name: SCOOTER
Classification Name: MOTORIZED 3-WHEELED VEHICLE, Class II, 21 CFR 890.3800

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 WU'S SCOOTER WT-T3H is an indoor / outdoor electric scooter that is battery operated. It has a base with three-wheeled, a seat, two 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 SCOOTER WT-T3D (K032488)

WU'S TECH CO., LTD.
NO. 225, YUAN-PIER ST., HSIN CHU CITY, CHINA (TAIWAN)
TEL: 886-5-5382105 FAX: 886-5-5382191
Homepage: www.wustech.com.tw Email: wustis@ms45.hinet.net

C.2 COMPARISON SUMMARY

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

The intended uses, weight limit 250 lbs, maximum speed 4 mph, safety climbing angle 8^0, back upholstery, and warranty period between the new device WT-T3H and the predicate device WT-T3D are all the same. Especially the electronic systems between two devices are all passed by the UL certificated, for instance the electronic controller, batteries and recharge. Besides, the back upholstery is the same material, and also passed the resistance ignition test by SGS. Thus the same safety level for the two devices is assured.

The new device is more simple and easy to use, thus the **major difference existing for new device is the overall dimension, the size of tires, weight, and the cruising range 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.

Based on the above the information and the analysis, we know that the subject device and the predicate devices have the same intended use, the same technological aspects and only minor dimensions or data 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

MAY 27 2009

WU's Tech Co., Ltd.
% ROC Chinese-European Industrial Research Soc.
Dr. Ke-Min Jen
No. 58. Fu-Chiun Street
Hsin-Chu City 30067
China (Taiwan)

Re: K091212
Trade/Device Name: WU'S ELECTRICAL SCOOTER, WT-T3H
Regulation Number: 21 CFR 890.3800
Regulation Names: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: April 17, 2009
Received: April 27, 2009

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K 091212

Device Name: *WU'S ELECTRICAL SCOOTER, WT-T3H*

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091212