K070817

APR 13 2007

LERADO CHINA LIMITED
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Chia Yi Hsien, Taiwan, ROC
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" 510(k) SUMMARY "

Submitter's Name: ***LERADO CHINA LIMITED***
Dong Sheng Road North Zhong Shan, CHINA

Date summary prepared: March 17, 2007

Device Name:

Proprietary Name:	LERADOTECH Scooter, SB
Common or Usual Name:	Electrical 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 LERADOTECH Scooter, SB is an indoor / outdoor Electrical Scooter that is battery operated. It has a base with four-wheeled with a seat. 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 Electrical Scooters, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

COMFORT Scooter LY-EW415 (K063032)

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Summary for substantial equivalence comparison:

The new device SB and the predicate device LY-EW415 are the same intended uses and warranty period, and the electronic systems between the two devices are all passed by the UL certificated. Except the recharger of the electronic systems, the two devices are the same suppliers. Especially, the two devices use the same controller and switching power supplier. 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 major difference existing for the two devices are tires size, weight limit, weight capabilities, and the dimensions for the new device are more agile and smaller than those of the predicate device. Thus the new device can drive smaller turning radius and safe climbing angle. The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

The maximum speed is 6.0 mph for the new device and 5.0 mph for the predicate device that are also under the 6 miles maximum speed limited. The speeds can be continuous adjusted by the throttle tiller. The operators can set the adequate speed according to their feeling and need, and the maximum speed differences do not mean any performance differences. They are substantially equivalent.

The cruising range of the new device is 36 km and 75 km for the predicate device. This is mainly due to the fact that the batteries for the new device are smaller. Certainly the real range depends on the practice environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

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. Thus 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

Lerado China Limited
% Republic of China
Chinese-European Industrial Research Society
Dr. Ke-Min Jen
Official Correspondent
No. 58, Fu-Chiun Street
Hsin-Chu City
China (Taiwan) 30067

APR 13 2007

Re: K070817
Trade/Device Name: LERADOTECH Scotter, SB
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: March 17, 2007
Received: March 26, 2007

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.

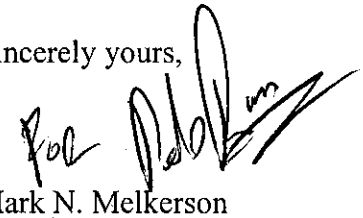
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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

Indications for Use

510 (K) Number (If Known): K

Device Name: *LERADOTECH SCOOTER, SB*

Indications for Use:

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

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

510(k) Number K070817

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)