K051473

AUG 3 1 2005

LERADO CHINA LIMITED

LERADO GROUP 隆成集團

Unit 18, 17F, China Merchants Tower, Shun Tak Center,
168-200 Connaught Rd., Central, HK, China
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" 510(k) SUMMARY "

Submitter's Name: ***LERADO CHINA LIMITED***
Unit 18, 17F, China Merchants Tower, Shun Tak Center, 168-200 Connaught Rd., Central, HK, China

Date summary prepared: May 29, 2005

Device Name:

Proprietary Name: LERADO, AVANTICARE Electrical Scooter, SM3021

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 LERADO, AVANTICARE Electrical Scooter SM3021 is an indoor / outdoor Electrical Scooter that is battery operated. It has a base with three-wheeled with a seat. The movement of the Wheelchair 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:

WU'S Wheeled Neo Scooter WT-T3B **(K023168)**

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Summary for substantial equivalence comparison:

The intended uses, back upholstery, armrest types, and warranty period between the new device SM3021 and the predicate device WT-T3B are all the same. Especially the electronic systems between two devices, except the electric controllers are the different suppliers, they are the same suppliers and all passed by the UL certificated, for instance the batteries, recharge and switching power supplier. Thus the same safety level for the two devices is assured.

The cruising range of the new device is 10 miles and 19 miles for the predicate device. This is mainly due to the fact that the batteries for the two devices 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.

The weight limit differences existing of the two scooters that the new device SM3021 weight limit is 300 lbs and the predicate device WT-T3B is 250 lbs. Besides, the maximum speed for the new device is 4.7 mph and 4 mph for the predicate device.

To sum up the mainly different of the two devices are only appearance dimensions, i.e., the overall dimensions, the size of wheels, seat dimensions, weight limit, and maximum speed. For the regular operator, these differences for the two devices do not lead to any performance differences, and the two devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2005

Lerado China Limited
c/o Dr. Jen Ke-Min
ROC Chinese-European Industrial Research Society
No. 58 Fu-Chiun Street
Hsin-Chu City, 30067, Taiwan, ROC

Re: K051473
Trade/Device Name: LERADO, AVANTICARE SCOOTER SM3021
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: August 8, 2005
Received: August 15, 2005

Dear Dr. Ke-Min:

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) 276-0115. 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
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: *LERADO, AVANTICARE SCOOTER SM3021*

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

510(k) Number K051473