FEB - 1 2005

LERADO OVERSEA LTD. TWN BRANCH(BVI)
No. 22, Kuang Fu Road, Chia Tai Industrial Tai Pao City,
Chia Yi Hsien, Taiwan, ROC
Tel: 886-5-2475520 Fax: 886-5-2379672
E-mail:edwardL@mail.lerado.com http:// www.lerado.com

K 050087

" 510(k) SUMMARY "

Submitter's Name: ***Lerado Oversea Ltd. Twn Branch (BVI)***
No. 22, Kuang Fu Road, Chia Tai Industrial,Tai Pao City, Chia Yi Hsien, 612, Taiwan, ROC

Date summary prepared: January 9, 2005

Device Name:

Proprietary Name: LERADO, AVANTICARE Power Wheelchair, PW-1800

Common or Usual Name: Powered Wheelchair

Classification Name: Powered Wheelchair, Class II,
21 CFR 890.3860

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 Power Wheelchair, PW-1800 is an indoor / outdoor Powered Wheelchair that is battery operated. It has a base with four-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 Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

SINON Power Wheelchair, SN-W401 (K040319)

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C.1 SUMMARY TABLE

ITEMS	SUBJECT DEVICE	PREDICATE DEVICE
BRAND NAME	AVANTICARE	*SINON*
MANUFACTURER	LERADO group	SINON Corporation
SERIES	Power wheelchair	Power wheelchair
MODEL NO	PW-1800	SN-W401
510K NO	TBA	**K040319**
INTENDED USE	SAME	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*
Frame	SAME	**FOLDABLE**
Overall dimension		
Overall length	SAME	102 cm / 40-1/8"
Overall width	SAME	61 cm / 24"
Overall height	SAME	99cm / 39"
Weight limit	SAME	115 kgs / 250 lbs
Maximum speed	SAME	4 mph / 6.4 km
Electronics	SAME	Dynamic DL cntroller
Batteries		
Quantity	Two	Two
Type	U1, 34Ah 12VDC* 2	U1, 38Ah 12VDC* 2
Range per charge	SAME	20 miles / 32 km

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C.2 COMPARISON SUMMARY

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

Owing to the predicate device SN-W401and the new device PW-1800 are made by the same designer that the same specifications for the two independent organizations to use the different brand that means the predicate device for the SINON corporation and the new device for the LERADO group. Thus, from the above table and appearances that **the intended use** between the two devices is the same. The **batteries** for the two devices are used the same brand and similar U1 type. The **control** systems for the two devices are from the same supplier, it is Dynamic DL 50 series type for the two devices. The **recharge** for the two devices are also used the same resource, HP8204B, and the recharger is certified by UL.

Besides, the same **foldable frame**, same removable **arm type**, same **weight limit,** same **maximum speed,** same **incline degree,** same **cruising range,** and **back upholstery** are the same material that also be passed the resistance ignition test by SGS. Even the two devices are the same **overall dimensions**, the same size of **wheels**, and **seat dimensions.**

To sum up, the mainly different of the two devices are only the two devices use the different but similar type batteries, i.e., the 34Ah for the new device, and the 38Ah for the predicate device. The two type batteries are from the same supplier, and also certified by UL. The differences for the two devices do not lead to any performance differences, thus they are substantially equivalent.

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

Ke-Min Jen
Lerado Oversea LTD. TWN Branch (BVI)
C/o Roc Chinese-European Industrial
No. 58, Fu-Chiun St.
Hsin-Chu City,
China, Taiwan 30067

FEB - 1 2005

Re: K050087
Device Name: Lerado, Acanticare Power Wheelchair, PW-1800
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: January 9, 2005
Received: January 13,2005

Dear Dr. Ke-Min 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.

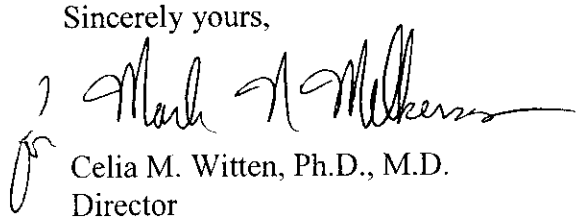
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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): K

Device Name: *LERADO, AVANTICARE Power Wheelchair, PW-1800*

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

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