DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2005

Lerado Oversea Ltd. TWN Branch (BVI)
C/o Dr. Ke-Min Jen
ROC Chinese-European Industrial
No. 58, Fu- Chiun Street
Hsin-Chu City
China (Taiwan) ROC 300

Re: K050290
Trade/Device Name: Lerado, Avanticare Mechanical Wheelchair, MS-8000
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: February 4, 2005
Received: February 7,2005

Dear Dr. Ke-Min Jen:

This letter corrects our substantially equivalent letter of February 18, 2005 regarding the trade name of the device. The error on the first letter was that we had Ms-800 instead of MS-8000.

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,

for 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

correct

Device Name: *LERADO. AVANTICARE Mechanical Wheelchair, MS-8000*

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)

Mark N Millman

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ivision of General, Restorative,

d Neurological Devices

510(k) Number K050290

18 2005

K050290

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

" 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: February 4,2005

Device Name:

Proprietary Name: LERADO,
AVANTICARE Mechanical Wheelchair, MS-8000

Common or Usual Name: Mechanical Wheelchair

Classification Name: Mechanical Wheelchair, Class I,
21 CFR 890.3850

Indications for Use:

The dcvice is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The AVANTICARE Mechanical Wheelchair, MS-8000 is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The dcvice can bc disassembled for transport and it is foldable easily. The device uses a standard sling type back and scat, the upholstery fabric meets the California Technical Bulletin CAL 117 standard for flame retardant.

Performance Testing:

AVANTICARE Mechanical Wheelchair, MS-8000 meet the applicable performance requirements as specified in ANSI/RESNA WC vol. I and ISO 7176 Wheelchair Standards.

Legally marketed device for substantial equivalence comparison:

PRO WALKER ML-300 Foldable Wheelchair (K041337)

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C.2 COMPARISON SUMMARY

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

From the above comparison table that the intended use and the weight limit **100kgs** between the two devices are the same. Mainframes of two devices are foldable. The overall dimensions are similar. Back upholstery material is also the same resistance -ignitability fabric and also meets the California Technical Bulletin CAL 117 standard for flame retardant. **The major differences existing are the overall dimension, and the size of tires are differences between the two devices.** The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

The seat heights between the new device and the predicate device have small difference, not leading to any safety hazard. The hanger and rear axle designs are same. The caster sizes are different. The predicate device's caster size is smaller and it can move more easily than the larger ones can. The weight and size of the new device is larger and the user can feel more comfortable to transport it. At last the optional accessories for the two devices are the same, thus the users have the same adversity to choose the needed accessories to accommodate their needs.

Based on the above the information and the analysis, we know that the new device and the predicate device have the same technological aspects and the same intended use, except for tiny appearance differences. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.