K043511

SOLEUS CHAMP INTERNATIONAL CO., LTD.

No.1-6, Kung Fu Rd., Liao Bao Village,
Ta Ya Hsiang, Taichung Hsien, Taiwan, 428, R.O.C.
Tel: 886-4-2560-1853 Fax: 886-4-2560-1142
E-mail: kspeed97@ms27.hinet.net

MAR 1 4 2005

" 510(k) SUMMARY "

Submitter's Name: ***SOLEUS CHAMP INTERNATIONAL CO., LTD.***
No.1-6, Kung Fu Rd., Liao Bao Village,Ta Ya Hsiang, Taichung Hsien, Taiwan, 428, R.O.C.

Date summary prepared: December 9, 2004

Device Name:

Proprietary Name:	SOLEUS POWERED WHEELCHAIR, FAD-2
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 restricte to a seated position.

Description of the device:

The SOLEUS POWERED WHEELCHAIR, FAD-2 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:

TEH LIN POWERED WHEELCHAIR MDG-201 (K022696)

SOLEUS CHAMP INTERNATIONAL CO., LTD.
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Summary for substantial equivalence comparison:

The electronic systems between two devices are the same suppliers and all passed by the UL certificated, for instance the batteries and recharge. Thus the same safety level for the two devices is assured. Besides, the **foldable frame** and **back upholstery** are the same material that also be passed the resistance ignition test by SGS. The major differences existing of the two Powered Wheelchairs are the different overall dimension, and the sizes of tires are differences between the two devices. The overall appearance differences are not safety aspect. Besides the two devices use the different electric controllers but all passed by EN 12184, WC / Vol.2:1998, Radiated Immunity: 30 V/m. So the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Dr. Ke Min Jen
Official Correspondence
Soleus Champ International Co., LTD.
No. 1-6, Kung Fu Rd., Liao Bao Village
Ta Ya Hsiang, Taichung Hsien, Taiwan, 428, ROC

Re: K043511
Trade/Device Name: Soleus Power Wheelchair, FAD-2
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: January 27, 2005
Received: February 22, 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,

for

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) Number (If Known): K043511

Device Name: *SOLEUS Power Wheelchair, FAD-2*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted t 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)

for Mark N. Milham

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

510(k) Number K043511