K034005

510(k) SUMMARY

SDS-4I NOV 1 8 2004

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87.

1. Applicant, Official Correspondent and Owner of 510(k)

Skylark Device& Systems Co., Ltd.
4F 34 Sec3 Chung Shan N. Road Taipei, Taiwan
Attn: George Chiang, Ph.D.
Tel: 886-33587677 ext301
Fax: 886-33550731

2. Name of Device

Trade/ Propriety Name: **SDS-4I**
Common/ Usual Name: Muscular and Interferential Current Stimulator
Classification name: 21 CFR 890.5850 " Powered Muscle stimulator" Class II.

3. Legally Market Predicate Devices

The **SDS-4I** is substantially equivalent to its legally marketed predecessor the EMS400 (K912642) IF- SD730 (K992652) and **RS-4i (K032652)**

4. Indications for Use:

Indication Use For EMS (Code 10, 20-22,30-33_)

Only Relax muscle Spasms
Prevent or retard disuse atrophy
Maintain or increase range of motion
Increase local blood circulation
Re-educate muscle
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Indication Use For IF (Code 11-18, 20-22,30-33)

For symptomatic relief and management of chronic pain and /or as an adjunctive treatment in the management of post -surgical and post-traumatic acute pain.

Powered muscle stimulators should only be used under medical supervision

5. **Device Description and Substantial Equivalence**

The **SDS-4I** like a number of legally marketed predicate devices incorporates traditional muscle stimulation and interferential current stimulation modalities into one unit. The **SDS-4I** is housed in a plastic enclosure. The front of the enclosure house character LCD display. The accessories provided with the **SDS-4I** include the output cable, the electrode pads, and the AC Charging Adapter.

The **SDS-4I** muscle stimulation modality operates at a specified 23 volts max (into a 500 ohm load) and 46mA max (into a 500 ohm load) with a pulse width of 520μs Max and a cycle frequency of 75 Hz (±5%). The pulse is Symmetrical bi-phasic. The waveform includes an on/off ramp, which slowly increases the pulse width to the desired setting.

The **SDS-4I** interferential modality operates at a specified 80 mA max (into a 500 ohm load). The carrier and interferential signals are sine wave symmetric, balanced outputs with zero net charge. The interferential modality can operate in a true interferential mode (4 pad mode) or the signals can be pre-mixed and only the pre-mixed signals sent to the patient (2 pad mode). The interference Signal frequency can be fixed (continuous) or carried based on three selections (variable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

George Chiang, Ph.D.
President
Skylark Device & Systems Co., Ltd.
4F, 34 Sec 1
Chung Shan N. Rd.
TaiPei, 100
China (Taiwan)

Re: K034005
Trade/Device Name: SDS-4I
Regulation Number: 21 CFR 890.5850 and Unclassified
Regulation Name: Powered muscle stimulator and Interferential Current stimulator
Regulatory Class: II
Product Code: IPF,LIH
Dated: October 8, 2004
Received: October 12, 2004

Dear Dr. Chiang:

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.

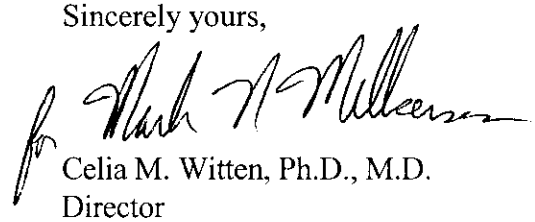
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/dsma/dsmamain.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): K034005

Device Name: SDS-4I

Indication Use for EMS (Code 10, 20-22,30-33)

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Powered muscle stimulators should only be used under medical supervision.

Prescription Use __X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

for Mark N Milhem

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

510(k) Number K034005