K102202

NOV 2 3 2010

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the GS 3000 510(k) premarket notification for and in accordance with FDA's *"Guidance Document for Powered Muscle Stimulator 510(k)s" June 9, 1999.*

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the GS 3000 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Applicant: EMSI
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Contact: Cherita James
M Squared Associates, Inc
901 King Street, Suite 200
Alexandria, VA 22314
Phone: 703-562-9800 Ext. 257
Facsimile: 703-562-9797

Date of submission: August 3, 2010

Proprietary Name: GS 3000

Common Name: Powered Muscle Stimulator

Classification Status: 21 CFR 890.5850

Product Code: IPF

Panel: Physical Medicine

Predicate Device: Skylark Device Company PGS 123 K946299

Device Description: The GS 3000 is a High Voltage Pulsed Galvanic Current (HVPGC) Stimulator which delivers stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The device has a twin peak monophasic waveform with a

5 μsec fixed duration. The current Amplitude is adjustable from 0-350 Volts (0~190V Max @ 500ohm resistance), with an adjustable pulse frequency range from 2-100 cycles per second.

The GS 3000 is a single channel device, with the option to set the active electrodes (treatment electrode) to either positive or negative polarity in relation to the dispersive electrode (closes patient circuit) and alternating or synchronous treatment mode selection. The device is powered by a 9 volt battery.

Intended Use: As prescribed by a physician for the following:
Relaxation of muscle spasm
Increasing local blood circulation
Maintaining or increasing range of motion
Preventing or retarding disuse atrophy
Muscle re-education
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Discussion of performance testing: Testing performed in accordance with the accepted FDA requirements of IEC 60601-1, found the GS 3000 met all applicable requirements. Based on the output measurements, calculations, and safety testing/inspection conducted; the GS 3000 is safe with respect to electrical leakage current, electrode and lead wire safety, as well as output current and power density. Testing performed in accordance with the accepted FDA requirements of IEC 60601-1-2, Medical Electrical Equipment, Part 1: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility- Requirements and Test, found the GS 3000 met all applicable requirements.

Technological Characteristics and Substantial Equivalence
Output specifications, device design, and waveforms demonstrated the GS 3000 to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Electrostim Medical Services, Inc.
% M Squared Associates, Inc.
Ms. Cherita James
901 King Street, Suite 200
Alexandria, Virginia 22314

NOV 2 3 2010

Re: K102202
Trade Name: GS 3000
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: October 27, 2010
Received: October 28, 2010

Dear Ms. James:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

K102202

510(k) Number: To be assigned

Device Name: GS 3000

Indications for Use: Relaxation of muscle spasm

NOV 23 2010

Increasing local blood circulation

Maintaining or increasing range of motion

Preventing or retarding disuse atrophy

Muscle re-education

Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Prescription Use ___X___ 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102202