

JUN 26 2012

510(k) SUMMARY

Mettler Sys*Stim 240, ME 240

Submitter's Name: Mettler Electronics Corp.

Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221 x331

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Contact: Christina Cayuela
QS/RA Manager

Date Prepared: September 29, 2011

Revised copy : March 27, 2012

Revised copy: May 23, 2012

Revised copy: June 25, 2012

Proposed Device Name:

- a. TRADE NAME: Sys*Stim 240
- b. CLASSIFICATION NAME: Powered Muscle Stimulator (890.5850), Transcutaneous Electrical Nerve Stimulator for pain relief (882.5890) and Infrared Lamp (890.5500)
- c. COMMON NAME: Combination Neuromuscular Stimulator and Low Level Light Therapy device

Predicate Devices:

- a. TRADE NAME: Chattanooga Group's Vectra Genisys - 2-channel electrotherapy system
- b. 510(k) Number: (K031077)
- c. TRADE NAME: Mettler Electronic Corp.'s Laser Sys*Stim 540, infrared lamp, therapeutic heating device
- d. 510(k) Number: (K043586)

Description of Proposed Device:

The new Sys*Stim® 240 neuromuscular stimulator features nine discrete waveforms designed to facilitate clinical versatility. Waveforms may be combined with on-off programs for neuromuscular education as well as frequency and amplitude modulation programs for optimal pain management.

New touch-sensitive technology has been used to make starting a treatment easy. The high-resolution color display allows clinicians to monitor all treatment parameters continuously. The patented M Wheel™ provides easy navigation through all of the menus.

Clinicians can add full-featured light therapy capabilities to the Sys*Stim 240 by purchasing either the cluster or laser applicator package. The laser applicator has an 80 mW, 785 nm, laser diode and the cluster emits 500 mW at 600 and 950 nm. Applicator holders are provided with each applicator and can be attached to the sides of the Sys*Stim 240.

Treatment protocols complete with electrode placement guidance allow clinicians to quickly program treatment parameters for their patients. There is even space to save special treatment protocols for each waveform and for light therapy.

The Sys*Stim 240 has an optional battery pack so that clinicians can take either electrical stimulation or light therapy to their patients. A carrying case is also available which holds the units and all the accessories necessary for therapy on the road.

Proposed Device Intended Use Statement:

Indications for Medium Frequency (Russian), Biphasic, High Volt Pulsed Current (HVPC), Interferential (4P) and Premodulated (2P) waveforms

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post surgical stimulation of calf muscles to prevent venous thrombosis

Additional Indications for Microcurrent, Interferential (4P), Premodulated (2P), Biphasic, and TENS waveforms

- Symptomatic relief and management of chronic, intractable pain
- Post-traumatic acute pain
- Post-surgical acute pain

Indications for DC (Direct Current) Mode

- Relaxation of muscle spasm

The laser and cluster applicators of the Sys*Stim 240 emit infrared energy for:

- Temporary increase in local blood circulation
- Temporary relief of minor muscle and joint aches, pains and stiffness
- Relaxation of muscles
- Temporary relief of Muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

Biocompatibility Certification: Electrodes to be provided with this device are the same as those previously submitted since 1997 with Mettler Electronics Corp. devices: Sonicator Plus 992/994 (K984142); Sys*Stim 226 (K964028); Sys*Stim 294 (K984114); and Sonicator Plus 930 (K013192).

Performance Testing: The Sys*Stim 240 has been certified for:

- ITS certification for ETL and C-ETL Listing
- Compliance with EMC, EN 60601-1-2: 2001 and FCC's 47 CFR, FCC Sub Part 18
- Compliance to IEC 60601-2-22: 2007
- Compliance to IEC 60825-1: 2007
- Compliance to IEC 62471: 2006
- Compliance to EN60601-2-10, (IEC 601-2-10) 2001

Comparison Table for Sys* Stim 240

510K Submission

Section 2

1. 510 K #	K	K031077
2. Device Name	Sys*Stim 240	Vectra Genisys
3. Manufacturer	Mettler Electronics	Encore Medical (Chattanooga Group)
4. Power Source	AC line or optional battery pack 10.8 V Lithium Ion	AC line or optional battery pack
Line Current Isolation	Yes	Yes
Patient Leakage Current (µA)		
Normal condition (ac)	78 (Less than 100 µA)	Less than 100 µA
Single fault condition (ac)	78 (Less than 500 µA)	Less than 500 µA
5. Number Of Output Modes	9 (one less output)	10
6. Channel(s)	2 Channel	2 Channel
Synchronous	1 & 2	1 & 2
Reciprocal	1 & 2	1 & 2
Other	Yes	Yes
7. Constant Current	Optional	Optional
Constant Voltage	Optional	Optional
8. Software / Firmware / Microprocessor Control	Yes	Yes
9. Automatic Overload Trip	Yes	Yes
Automatic Over Current Trip	Yes	Warning only, Overcurrent
10. Automatic No Load Trip	Yes	Warning only, Bad electrode contact
11. Automatic Shut Off	Yes	Yes
12. Patient Override Control Method	Yes Patient interrupt switch	Yes Patient interrupt switch
13. Indicator Display		
On / Off Status	Yes	Yes
Low Battery Indicator	Yes	Yes
Voltage / Current Level	Yes	Yes
14. Timer Display: (Stimulator)	0 – 60 minutes for stimulation Auto based on dosage for light therapy	0 – 60 minutes
15. Standards		
ISO 14971 : 2000	Yes	Yes
UL 60601-1	Yes	Yes
CSA C22.2 NO 601.1-M90	Yes	Yes
IEC/EN 60601-1	Yes	Yes
IEC/EN 60601-1-2	Yes	Yes
IEC/EN 60601-2-10	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
16. Compliance with 21 CFR 898	Yes	Yes
17. Weight (lbs.)	4.5 lb / 5.50 lb with Battery (Lighter wt)	7
18. Dimensions (in.) H x W x L	8 in (H) x 8 in (W) x 13 in (L)	8.8 x 11.375 x 12.75
19. Housing Materials & Construction	ABS Plastic	ABS Plastic

Explanation of Differences on the Comparison Table for the Sys*Stim® 240

Item	Mettler	Chattanooga	Explanation
5. Number of output modes	9	10	Mettler does not have Chattanooga's proprietary VMS burst
9. Automatic Over Current Trip	Yes	Warning only, Overcurrent	On an error such as this one, Mettler chooses to stop all output in the interest of patient safety.
10. Automatic No Load Trip	Yes	Warning only, Bad electrode contact	Mettler chooses patient safety, by requiring the clinician to fix the contact issue and then restart the system, to assure there are no excess outputs.
17. Weight	4.5 lbs.	7 lbs.	Different design criteria, no effect on function
18. Dimensions	8 x 8 x 13	8.8 x 11.375 x 12.75	Different design criteria, no effect on function



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Mettler Electronics Corporation
% Ms. Christina Cayuela
QS/RA Manager
1333 South Claudina Street
Anaheim, California 92805

JUN 26 2012

Re: K113017
Trade/Device Name: SYS*stim 240
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, ILY, GZJ, LIH
Dated: May 26, 2012
Received: June 04, 2012

Dear Ms. Cayuela:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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,



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

Enclosure

Indications for Use

510(k) Number (if known): K113017

Device Name: Sys*Stim® 240, Model ME240

1. Indications for Medium Frequency (Russian), Biphasic, High Volt Pulsed Current (HVPC), Interferential (4P) and Premodulated (2P) waveforms

- Relaxation of muscle spasms
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2. Additional indications for Microcurrent, Interferential (4P), Premodulated (2P), Biphasic and TENS waveforms

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4. The laser and cluster applicators of the Sys*Stim 240 emit infrared energy for:

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- Temporary relief of minor pain and stiffness associated with arthritis

Prescription Use X

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113017