DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 9, 2017

StimMed, LLC
% Marlene Barton
President
Wright Regulatory Consulting, Inc.
3900 Galt Ocean Drive, Apt. 2501
Fort Lauderdale, Florida 33308

Re: K171071
Trade/Device Name: StimSox™ System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: August 7, 2017
Received: August 8, 2017

Dear Ms. Barton:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171071

Device Name
StimSox™ System

Indications for Use *(Describe)*
The StimSox™ System is indicated to temporarily increase local blood circulation in healthy leg muscles and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER:

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Date Prepared: August 9, 2017

II. DEVICE

Name of Device: StimSox™ System
Common or Usual Name: Powered Muscle Stimulator
Classification Name: Powered Muscle Stimulator for Re-education of Muscles (21 CFR 870.5850)
Regulatory Class: Class II
Product Code: IPF

III. PREDICATE DEVICES

Device Name (Primary): Actegy's Revitive IX
510(k) Number: K123354

Device Name (Secondary): StimSox™ System
510(k) Number: K151922

To the best of our knowledge, the predicate devices have not been the subject of any design related recalls.

IV. DEVICE DESCRIPTION

a. Device Identification

The StimSox™ System is comprised of a battery powered electrical stimulator, disposable gel electrodes, two left foot boots, two right foot boots, and three AAA batteries.

b. Device Characteristics

The StimSox™ Stimulator software is embedded firmware written for a microcontroller. The software in the StimSox™ Stimulator is for input controls and output display. There is no operating system. It is a real-time loop that is event driven based on the three buttons on the box.

c. Environment of Use

The StimSox™ System is designed to be used in healthcare facilities or home use. The StimSox™ System is intended to be provided to the patient by a medical practitioner.

d. Principle of Operation

The StimSox™ System is a powered external stimulator. An electrical signal generator produces a square wave pattern of variable frequency, duration, intensity, ramp time, and stimulation on-off cycle. Surface electrodes are positioned over the foot muscles and are attached to the stimulator. The stimulator is programmed in a manner to stimulate the foot muscles. Stimulation can lead to a temporary increase in the popliteal and femoral venous blood flow. This increase in blood flow may help reduce the risk of venous thrombosis.

e. Materials of Use

The patient contacting gel electrodes provided with the StimSox™ System are commercially cleared gel electrodes. The gel electrode materials were successfully tested per ISO 10993 for Cytotoxicity, Irritation and Sensitization. The results verified the gel electrode materials to be non-cytotoxic, non-irritating and non-sensitizing. The gel electrodes are intended to be disposed of after one use (24 hours).

The material that makes up the patient contacting portion of the boot is made of medical grade100% Nylon Fabric with a Polyester Foam Core and Nylon Tricot Backing Nylon.

f. Key Performance Specifications

The StimSox™ Stimulator is a biphasic electrical stimulator that outputs a stimulating waveform in a prescribed pattern. The stimulator attaches to the outside of the StimSox™ boot. The key features of this stimulator are:

1. Battery powered with certified electronics.
2. Protected from inadvertent changes of stimulation level using timed auto-lock.
3. Simple user interface.
4. Designed to be worn through all phases of immobility to full mobility while performing normal daily activity, with the exception of driving or bathing.

V. INDICATIONS FOR USE

The StimSox™ System is indicated to temporarily increase local blood circulation in healthy leg muscles and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison Feature	**Actegy's Revitive IX (Primary Predicate)**	**StimSox™ (Secondary Predicate)**	**StimSox™ (Subject of this 510(K))**
510(k) Number	K123354	K151922	K171071
Manufacturer	Actegy Ltd.	StimMed, LLC	StimMed, LLC
Indications for Use	• Relaxation of muscle spasms; • Prevention or retardation of disuse atrophy; • Increasing local blood circulation; • Muscle re-education; • Immediate post-surgical stimulation of	To temporarily increase local blood circulation in healthy leg muscles.	• To temporarily increase local blood circulation in healthy leg muscles; and • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Comparison Feature	Actegy's Revitive IX (Primary Predicate)	StimSox™ (Secondary Predicate)	StimSox™ (Subject of this 510(K))
	calf muscles to prevent venous thrombosis; and • Maintaining or increasing range of motion.		
Mode of Stimulation	Moving venous blood from the veins in the foot anterograde (forward or proximally) up the lower extremity to prevent stagnation or pooling of venous blood flow in calf veins	Moving venous blood from the veins in the foot anterograde (forward or proximally) up the lower extremity to prevent stagnation or pooling of venous blood flow in calf veins	Moving venous blood from the veins in the foot anterograde (forward or proximally) up the lower extremity to prevent stagnation or pooling of venous blood flow in calf veins
Technology	Electrical stimulation	Electrical stimulation	Electrical stimulation
Power Source	3.6Vdc Lithium Ion Polymer rechargeable battery	3 batteries type AAA Non-recharge	3 batteries type AAA Non-rechargeable
Method of Line Current Isolation	Transformer isolation	Not Applicable	Not Applicable
Patient Leakage Current: -Normal Condition -Single Fault Condition	 Patient leakage: 6.21 µA max, Enclosure leakage : 5.99 µA Patient leakage: 8.36 µA max, Enclosure leakage: 7:95 µA max	Not Applicable	Not Applicable
Number of Output Modes	One	One	One
Number of Output Channels -Synchronous or Alternating -Method of Channel Isolation	2 (1 for sole, 1 for body pads) Alternating Transformer	One Not Applicable Not Applicable	One Not Applicable Not Applicable

Comparison Feature	**Actegy's Revitive IX (Primary Predicate)**	**StimSox™ (Secondary Predicate)**	**StimSox™ (Subject of this 510(K))**
Regulated Current or Regulated Voltage	Regulated up to 150V	Current	Current
Software / Firmware / Microprocessor Control	Yes	Yes	Yes
Automatic Overload Trip	No	Yes	Yes
Automatic No-Load Trip	No	Yes	Yes
Automatic Shut Off	Yes	Yes	Yes
Patient Override Control	Yes	No	No
Indicator Display: -On/Off Status -Low Battery -Voltage/Current Level	 Yes N/A Yes	 Yes Yes Yes	 Yes Yes Yes
Timer Range (minutes)	1 – 60 minutes	N/A	N/A
Compliance with voluntary standards	EMDD (93/42EEC), EN60601-1-2:2007	ISO 10993-1 ISO10993-12 ISO 10993-10 IEC 60601-1-6/A1:2013 IEC 62366/A1:2014 IEC 60602-1-11:2010 IEC 60601-2-10:2012 EN 60601-1-2:2007 (Ed. 3.0) EN 60602-2-10: 2012	ISO 10993-1 ISO10993-12 ISO 10993-10 IEC 606011-6/A1:2013 IEC 62366/A1:2014 IEC 60602-1-11:2010 IEC 60601-2-10:2012 EN 60601-1-2:2007 (Ed. 3.0) EN 60602-2-10: 2012
Compliance with 21 CFR 898	Complies	Not Applicable	Not Applicable
Weight	1725g (not including the PSU)	102.55g with batteries	102.55g with batteries

Comparison Feature	Actegy's Revitive IX (Primary Predicate)	StimSox™ (Secondary Predicate)	StimSox™ (Subject of this 510(K))
Dimensions (inches) [W x H x D]	360mm x 75mm overall height	3.62x2.87x1.10	3.62x2.87x1.10
Housing Materials and Construction	Casing/body ABS, footpads NBR	Plastic Enclosure	Plastic Enclosure

VII. COMPARISON OF OUTPUT SPECIFICATIONS

Output Specifications	Actegy's Revitive IX (Primary Predicate)	StimSox™ (Secondary Predicate)	StimSox™ (Subject of this 510(K))
Waveform (e.g., pulsed monophasic, biphasic)	monophasic	diphasic	diphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	rectangular	rectangular	rectangular
Maximum Output Voltage (specify units) (± 10%)	35V @ 500 Ω 103V @2 kΩ 135V @ 10 kΩ	15V @500 Ω 60V @2 kΩ 133V@10kΩ	15V @500 Ω 60V @2 kΩ 133V@10kΩ
Maximum Output Current (specify units) (±10%)	70mA@ 500 Ω 52mA@2 kΩ 14mA@10 kΩ	30mA@500Ω 30mA@2kΩ 13.3mA@10kΩ	30mA@500Ω 30mA@2kΩ 13.3mA@10kΩ
Pulse Width (specify units)	Not disclosed	50µS	150µS
Frequency (Hz)	Not disclosed	50Hz	50Hz
For interferential modes only: Beat Frequency (Hz)	Not disclosed	N/A	N/A
For multiphasic waveforms only: Symmetrical phases?	N/A	Yes	Yes
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	N/A	300µS	300µS

Output Specifications	Actegy's Revitive IX (Primary Predicate)	StimSox™ (Secondary Predicate)	StimSox™ (Subject of this 510(K))
Net Charge (μC per pulse) (If zero, state method of achieving zero net charge)	0.004@500 Ω	4.5 @500 Ω	4.5 @500 Ω
Maximum Phase Charge, (μC)	52@500 Ω	5400@500 Ω	5400@500 Ω
Maximum Current Density, (mA/cm²)	0.031@500 Ω	1.53@500 Ω	1.53@500 Ω
Maximum Power Density, (W/cm²) (using smallest electrode conductive surface area)	0.79@500 Ω	0.023@500 Ω	0.023@500 Ω
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	 195 – 1092 0.11 – 0.29 1.91 – 8.35 0.56 – 0.89	 600 0.0167 12 0.20	 600 0.0167 12 0.20
ON Time (seconds)	1.90 – 8.40	12	12
OFF Time (seconds)	1.00 – 1.50	48	48

VIII. CLINICAL EVALUATION

Peer-reviewed journal articles were reviewed to support the safety and efficacy of the StimSox™ technology for the expanded indication of immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. The articles are provided along with a summary below:

1. James J. Czyrny, Robert E. Kaplan, Gregory E. Wilding, Christopher H. Purdy, and Jack Hirsh. Electrical Foot Stimulation: A Potential New Method of Deep Venous Thrombosis Prophylaxis. Vascular, Vol. 18, No. 1, pp. 20–27, 2010.

   Czyrny JJ, et al. concluded that short-term electrical foot stimulation is at least as effective as knee-high intermittent pneumatic compression in increasing popliteal and femoral blood flow velocity.

2. Robert E. Kaplan, James J. Czyrny, Tat S. Fung, John D. Unsworth, Jack Hirsh. Electrical Foot Stimulation and Implications for the Prevention of Venous Thromboembolic Disease. Thromb Haemost 2002; 88:200-4.

   Kaplan RE, et al. concluded that mild electrical stimulation of the feet, as well as the calf, is a safe effective and convenient method for counteracting venous stasis and therefore has the potential to reduce the risk of deep vein thrombosis and pulmonary embolism for subjects who are immobilized.

   Overall Conclusion

   These studies used comparable stimulation parameters as the StimSox System and demonstrated that stimulation on sole of the foot can lead to a temporary increase in local blood circulation in calf muscles. This increase in blood flow may help reduce the risk of venous thrombosis.

IX. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- Risk analysis results demonstrate acceptable potential and mitigated hazards
- Electrical Safety and Electromagnetic Compatibility (EMC)
  - IEC 60601-1-6/A1:2013
  - IEC 62366/A1:2014
  - IEC 60602-1-11:2010
  - EN 60601-1-2:2007 (Ed. 3.0)
  - EN 60601-2-10: 2012
- Biocompatibility for Gel Electrodes
  - Sensitization
  - Irritation
  - Cytotoxicity
- Software Verification

The device is identical in design compared to the secondary predicate device K151922. The electrical safety, EMC, biocompatibility, and software were leveraged from that submission. The data provided demonstrates that the StimSox™ System is substantially equivalent to its predicate, and raises no new safety or effectiveness issues.

X. CONCLUSION

The performance data and Risk Analysis support the safety of the device and the software verification and validation provide evidence that the StimSox™ System will perform as intended for the specified use conditions. The StimSox™ is designed and verified for performance and safety. The performance of the StimSox™ System is determined to be substantially equivalent in indications, technical functions and operation to the predicate device. The Risk Analysis does not demonstrate any design or safety concerns.