



Food and Drug Administration
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April 15, 2016

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

Re: K151922
Trade/Device Name: StimSox™ System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 11, 2016
Received: April 12, 2016

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 yours,

Michael J. Hoffmann -A

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

Indications for Use

510(k) Number (if known)

K151922

Device Name

StimSox(TM) System

Indications for Use (Describe)

To temporarily increase local blood circulation in healthy leg muscles.

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
StimSox™ System

I. SUBMITTER:

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Date Prepared: April 13, 2016

II. DEVICE

Name of Device: StimSox™ System
Common or Usual Name: Powered Muscle Stimulator
Classification Name: Powered Muscle Stimulator (21 CFR 890.5850)
Regulatory Class: Class II
Product Code: IPF

III. PREDICATE DEVICE

Device Name: AMD 6605 TENS/NMES Stimulator
510(k) Number: K092990

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

IV. DEVICE DESCRIPTION

Device Identification

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

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.

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.

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.

The material that makes up the patient contacting portion of the boot is made of medical grade 100% Nylon Fabric with a Polyester Foam Core and Nylon Tricot Backing Nylon. Each boot is intended to be used for up to 7 days of use.

Key Performance Specifications

The duration of patient use for the StimSox™ System will typically be 10 – 14 days as recommended by the ACCP (American College of Chest Physicians) or as prescribed by the patient's medical provider.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison Feature	StimSox™ K151922	AMD 6605 K092990	Justification
Manufacturer	StimMed, LLC	Advantageous Medical Devices, LLC	N/A
Indications for Use	The StimSox™ System is indicated to temporarily increase local blood circulation in healthy leg muscles.	<p>Indications for TENS function:</p> <ul style="list-style-type: none"> • Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain or post-traumatic acute pain. <p>Indications for NMES function:</p> <ul style="list-style-type: none"> • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis 	Although the predicate has more claims than the subject device, the IFU of the subject device is within the scope of the NMES function of the predicate device.

Comparison Feature	StimSox™ K151922	AMD 6605 K092990	Justification
		<ul style="list-style-type: none"> • Maintaining or increasing range of motion 	
Electrodes	2	4 (Two electrodes per channel)	The number of electrodes is a consequence of the number of channels.
Electrode type	<p>Gel Electrode One 2 inch round self-adhering disposable and One 4x2 inch oval self-adhering disposable</p> <p>Comfort Gel A 032 Model 807</p>	<p>Gel Electrode 2 inch round self-adhering reusable</p> <p>AmGEL AG702 (Now AG735).</p>	Comfort Gel A 032 Model 807 is cleared under K072799 and K101576
Waveform	Biphasic	Monophasic	There is a requirement for electrical stimulators to have no D.C. component or a rationalization why there is a D.C. component (60601-2-10). The StimSox™ System does not have a D.C. component because it is biphasic. The predicate is listed as monophasic and thus must have a D.C. component.
Maximum Intensity	30 mA	70 mA	The predicate supports more than twice the maximum current. Based on the Clinical Data Review, this limited output is sufficient to meet the clinical needs for the StimSox™ System.
Current step size	1 mA steps	0.5 mA steps	The differences in current increments, are small and do not affect the desired clinical response, which is a small contraction of the plantar muscles of the foot. The StimSox validation study demonstrated that the 1.0mA increments were safe and effective in achieving the desired clinical response.
Power Source	3 batteries type AAA Non-rechargeable	4 batteries type AAA alkaline or rechargeable Ni MH	The line isolation of the AMD device is for units that also plug in. This difference is not significant as it does not affect the effectiveness or safety of the device as the StimSox™ System will not need the plug in feature.
Method of Line Current Isolation	Not Applicable	Unknown	The StimSox™ System is battery powered.
Patient Leakage Current: -Normal Condition	Not Applicable	Not Applicable	There is no patient leakage because the StimSox stimulator is battery powered.

Comparison Feature	StimSox™ K151922	AMD 6605 K092990	Justification
-Single Fault Condition		Not Applicable Not Applicable	
Number of Output Modes	One	Three	The predicate device is indicated for more uses than the StimSox™ System.
Number of Output Channels	One	Two	The number of channels is less on the StimSox™ System because it has reduced functionality when compared to the predicate.
-Synchronous or Alternating	Not Applicable	Unknown	
-Method of Channel Isolation	Not Applicable	Unknown	
Regulated Current or Regulated Voltage	Current	Current	Same
Software/Firmware/Microprocessor Control	Yes	Yes	Same
Automatic Overload Trip	Yes	Unknown	This difference has no effect on the safety and effectiveness of the device.
Automatic No-Load Trip	Yes	Unknown	This difference has no effect on the safety and effectiveness of the device.
Automatic Shut Off	Yes	Yes	Same
Patient Override Control	No	Unknown	The patient can remove the StimSox stimulator or turn it down.
Indicator Display:			The StimSox User Manual instructs the user to change the batteries. Not including a low battery indicator will not affect the Safety or Effectiveness of the stimulator.
-On/Off Status	Yes	Yes	
-Low Battery	No	Yes	
-Voltage/Current Level	Yes	Yes	
Timer Range (minutes)	N/A	0 to 90	The StimSox device is continuous
Compliance with Standards	ISO 10993-1 ISO10993-10 ISO 10993-12 IEC 60601-1-6/A1:2013 IEC 62366/A1:2014 IEC 60602-1-11:2010 IEC 60601-2-10:2012 IEC 60601-1-2:2007 (Ed. 3.0) IEC 60602-2-10:2012	ISO 10993-1 ISO 10993-12 ISO 10993-10 IEC 60601-1:1988+A1:1991+A2:1995 IEC 60601+1-2:2001/A:1:2004 IEC 60601-14:2000 IEC 60601-1-6;2004	The standards applied to the StimSox™ System are the more recent versions of the predicate.

Comparison Feature	StimSox™ K151922	AMD 6605 K092990	Justification
Compliance with 21 CFR 898	N/A	Unknown	The design of the StimSox™ System does not include lead wires.
Weight	102.55g with batteries	115g with batteries	This difference has no effect on the Safety or Effectiveness of the device.
Dimensions (inches) [W x H x D]	3.62x2.87x1.10	5.55x2.48x0.70	This difference has no effect on the Safety or Effectiveness of the device.
Housing Materials and Construction	Plastic Enclosure	Plastic Enclosure	Same
Keyboard lock	Automatic	Automatic	Same
Programs	1 preset	10 preset and 10 user adjustable	The predicate device includes more indications for use.
Time of treatment	4-18 hours	Treatment time with auto shut off	The StimSox design is a simpler device with a specific indication of only the foot muscles. The predicate is a general use device that can be used on various voluntary muscles.

Electrode placement differences:

The predicate electrodes are placed on the calf muscles while the subject device electrodes are placed on the foot. However, in one study (*Thrombosis and Haemostasis. Kaplan RE et al, Throm Haemost 2002;88:2004*), stimulation of the foot vs. stimulation of the calf muscles were compared. It was found that the electrodes on the foot were more comfortable and increased the venous femoral and popliteal blood flow for both calf and plantar muscles. This study was not conducted with the predicate, however, it serves as a rationale that subject device can be at least as safe and effective as the predicate device given similar parameters of operation.

Similarities:

Both the StimSox™ System and the predicate device have the following similarities:

- Use commercially available gel electrodes
- Battery operated (Direct Current (DC))
- Regulated current
- Include an indicator display
- Provide preset programs
- Include continuous treatment time

Conclusion

The StimSox™ stimulator has the same technological characteristics as the predicate – just fewer options for treatment programming as it is designed for NMES and the

predicate is 510 (k) cleared for TENS and NMES. These differences do not raise any additional risks of safety or effectiveness.

VII. 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
 - IEC 60601-1-2:2007 (Ed. 3.0)
 - IEC 60601-2-10: 2012
- Biocompatibility for Gel Electrodes
 - Sensitization
 - Irritation
 - Cytotoxicity
- Software Verification

The data provided demonstrates that the StimSox™ System is substantially equivalent to its predicate, and raises no new safety or effectiveness issues.

VIII. OVERALL CONCLUSIONS

The performance data provide evidence that the StimSox™ System will perform as intended for the specified use conditions. The StimSox™ System 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.