



Food and Drug Administration
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February 22, 2017

Sven Bieler, PhD
Regulatory Affairs
BEMER Int. AG
Austrasse 15
Triesen, 9495 Liechtenstein

Re: K151834

Trade/Device Name: BEMER Classic Set, BEMER Pro-Set
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 23, 2017
Received: January 23, 2017

Dear Dr. Bieler:

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 and Part 809); 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 and Part 809), 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 -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

Indications for Use

510(k) Number (if known)

K151834

Device Name

BEMER Classic Set and BEMER Pro-Set

Indications for Use (Describe)

- To temporarily increase local blood circulation in healthy leg muscles
- To stimulate healthy muscles in order to improve and facilitate muscle performance

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.

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6. 510(K) SUMMARY

The following information is provided as required by 21 CFR 807.92 for BEMER International, AG's BEMER Therapy Systems 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: BEMER International, AG
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Date of Submission:	February 22, 2017
Proprietary Name(s):	BEMER Classic Set and BEMER Pro-Set
Common Name:	Powered Muscle Stimulator, Powered Muscle Stimulator for Muscle Conditioning
Regulatory Class:	II
Regulation:	21 CFR 890.5850
Panel:	Physical Medicine
Product Codes:	NGX
Predicate Device:	K143207, Revitive IX (OTC)
Reference Device:	K973929, Neotonus Model 1000 Muscle Stimulator System

Device Description:

BEMER therapy systems are a family of noninvasive physical medicine devices that can be used as a supportive therapy to increase local blood circulation. BEMER therapy is offered in two system options—Classic and Professional. Both systems consist of a B.BOX console, a set of BEMER signal applicators, power pack, B.SCAN indicator and accessories for attachment. The B.PAD and B.SPOT applicators have been cleared for use in this submission.

BEMER systems improve local blood distribution via electromagnetic stimulatory principles. The resulting increase in local blood distribution can broadly benefit patients. The indications for use allow the application to increase local blood circulation or stimulate healthy muscles in order to improve and facilitate muscle performance.

BEMER therapy systems are substantially equivalent to other legally marketed over-the-counter devices within physical medicine classifications NGX (Powered Muscle stimulator). Generally, these are non-invasive and reusable muscle conditioning devices that stimulate muscle contractile properties, force output and/or fatigue resistance. These devices also improve local blood circulation in muscle tissue. These devices create electric stimulation either via direct application of electric current or via induction of electrical stimulation within the tissue by application of magnetic flux. All are used for therapy regimes lasting days to weeks with one or more individual treatments per day lasting generally less than an hour. All are designed for patient-managed self-use in a home setting.

BEMER Therapy Systems utilize induction of microcurrents to tissue. Like the reference device, this non-invasive electromagnetic stimulation improves muscle activity induced by electromagnetic stimulation.

Intended Use:

BEMER therapy systems (BEMER Classic Set, BEMER Pro-Set) are indicated for:

- To temporarily increase local blood circulation in healthy leg muscles
- To stimulate healthy muscles in order to improve and facilitate muscle performance

Performance Testing:

BEMER therapy systems are compliant with the following standards and have outputs that are within the same range as the predicate devices:

STANDARD	DESCRIPTION
510(k) Declaration of Conformity Standards	
IEC/EN 60601-1:2007	Medical Electrical Equipment, Part 1, General Requirements for Safety
IEC 60601-1-2:2014	Medical Electrical Equipment, Part 1-2, General Requirement for Safety. Electromagnetic Compatibility
IEC/EN 60601-1-4:2001	Medical Electrical Equipment, Part 1-4, Collateral Standard: Programmable electrical medical systems.
IEC/EN 60601-1-6: 3rd	Medical Electrical Equipment, Part 1-6, Usability
IEC/EN 60601-1-11: 2010	Medical Electrical Equipment, Part 1-11, General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC/EN 62366	Medical devices – Application of usability engineering to medical devices
EN ISO 10993-1:2009	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing <i>(Overall plan and requirements established internally, specific tests conducted by 3rd party, see Section 16)</i>
General Compliance Standards	
EN ISO 13485:2012	Medical Devices, Quality Management Systems, Requirements for Regulatory Purposes
EN ISO 14971	Application of risk management to medical products
IEC/EN 62304	Software life cycle processes

Technical and Performance Comparison:

The subject and predicate devices are all non-invasive, reusable, and used as therapies for wide-ranging conditions resulting in pain, atrophy, and reduced circulation (loss of vascular and muscle tone). All employ the same general principles of tissue and cellular stimulation; some stimulate via direct electrical stimulation, while others induce electrical stimulation within the tissue by the application of magnetic flux.

Table 12.1, BEMER Therapy Systems Substantial Equivalence Summary Table

	BEMER Therapy Systems SUBJECT DEVICE	Revitive IX (K143207) Predicate Device	Neotonus MS-101 Magnetic Muscle Stim. System (K973929) Reference Device	Comments
Classification Code(s)	Primary: Powered Muscle Stimulator NGX 890.5850	Primary: Powered Muscle Stimulator NGX 890.5850 Secondary: Transcutaneous Nerve Stimulator NUH 882.5890	Powered Muscle Stimulator IPF 890.5850	
Indications for Use	<p><i>[Pending] The BEMER therapy is indicated:</i></p> <p><i>To temporarily increase local blood circulation in healthy leg muscles.</i></p> <ul style="list-style-type: none"> - <i>To stimulate healthy muscles in order to improve and facilitate muscle performance.</i> 	<p>To temporarily increase local blood circulation in healthy leg muscles.</p> <ul style="list-style-type: none"> - To stimulate healthy muscles in order to improve and facilitate muscle performance. - For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties. 	<p>The Neotonus MS-101 Magnetic Muscle Stimulator System is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Neotonus MS-101 is indicated for use in stimulating neuromuscular tissues for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: 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, maintaining or increasing range of</p>	

	BEMER	Revitive IX (K143207)	Neotonus (K973929)	
PRIMARY MODE OF ACTION	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via skin electrodes	Non-invasive tissue stimulation via magnetic field induction	
Waveform	Pulsed asymmetric, constant amplitude during treatment	Pulsed symmetrical, constant amplitude during treatment	Unknown	Minor difference, no impact on safety and effectiveness.
Shape	Sinusoidal, monopolar	Rectangular, bipolar	Unknown	Minor difference, no impact on safety and effectiveness
Pulse repetition rate	All accessories: 10-30Hz	Foot: 20-53Hz Body: 35-46Hz	1-55Hz	Minor difference, no impact on safety and effectiveness
Single pulse duration	All accessories: 10 - 33 μ S	Foot: 0.4 - 7.5 μ S Body: 1.4 - 33.6 μ S	18-1000 μ S	Minor difference, no impact on safety and effectiveness
Maximum Power density applied::	All accessories: 35 - 100 μ T	Foot: 0.023 mA/cm ² Body: 0.082 mA/cm ²	1-100%	Minor difference, no impact on safety and effectiveness
Maximum output voltage	N/A	@500 Ω : 20-32V @2k Ω : 95-118V @10k Ω : 138-169V	Unknown	Safety: The subject device does not directly apply voltage to the human body. Therefore, no new hazards were identified.
Maximum Output Current	Current directly applied to the patient's body All accessories: <5mA (acc. to IEC 60601-1)	Current directly applied to the patient's body: @500 Ω : 40-64mA @2k Ω : 48-59mA @10k Ω : 14-17mA	Unknown	Effectiveness: As the mode of action differs from direct induction (predicate device) to indirect induction (subject device), safety and effectiveness must be proven via a comparative series of measurements

Treatment mode, Treatment Mode, Treatment Time				
Basic Plan Treatment	Local applicator (B:PAD, B.SPOT, max. 2 applicators connected to the device) Local treatment on skeletal muscles – to be used in separate locations (not at the same time) Treatment area restricted by applicator geometry Intensities:1-10 Treatment time: 8min	Body Pads (max. 2 pairs of conductive pads) local treatment on skeletal muscles no distance restriction between conductible body pads Intensities: 1-99 Treatment time: 1-30min		Minor difference, no impact on safety and effectiveness
Optional Local Treatment	Local applicator (B:PAD, B.SPOT, max. 2 applicators connected to the device) Local treatment on skeletal muscles – to be used in separate locations (not at the same time) Treatment area restricted by applicator geometry Intensities:3-10 Treatment time: 8 - 20min	Body Pads (max. 2 pairs) plus Feet Pad with IsoRocker 2 plates for feet, 4 conductive pads Both feet and lower extremities, whole body application possible Intensities: 1-99 Treatment time: 1-30min		Minor difference, no impact on safety and effectiveness
Model	B.BOX Professional B.BOX Classic	RIX		
Weight	1.3kg (B.BOX Classic) 1.4kg (B.BOX Professional)	1.725kg		Minor difference, no impact on safety and effectiveness
Dimensions	32 x 32 x 7 cm	Ø360mm x 75mm (isoRocker enabled) Ø360mm x 100.5mm (isoRocker disabled)		Minor difference, no impact on safety and effectiveness
Power Consumption	Max 30 Watt	5W		Minor difference, no impact on safety and effectiveness

AC Adaptor – UL (Underwriters Laboratories) Safety Mark				
Input Output	100-240 VAC 50-60 Hz, 0.6A 15 Vdc, 2.0A Optional 7.2 V Li-Ion battery	100-240V, 50/60Hz, 0.18A. 5.0Vdc, 1.0A		Minor difference, no impact on safety and effectiveness
Biocompatibility	Yes	Yes	Yes	
Number of output modes	1	1	1	
Number of output channels and ports	2 for each	2 (1 for foot, 1 for body pads), 3 output ports (2 pairs of body pads can be run at same time on same channel)	1	
Software / Firmware / Microprocessor controlled	Yes	Yes		
Voltage / Current Level	1-10 intensity indicator	1-99 intensity indicator		Minor difference, no impact on safety and effectiveness
Timer Range	8-20 minutes	1-60 minutes		Minor difference, no impact on safety and effectiveness
Compliance with voluntary standards	IEC60601-1 IEC 60601-1-2 EN 60601-1-6 EN 62366 EN 60601-1-11	EN 60601-1 EN 60601-1-2 EN60601-1-11		
Compliance with European Medical device Directive (93/42/EEC)	Yes	Yes		
Sterilization	Not provided sterile	Not provided sterile	Not provided sterile	

Usability:

A Usability study was conducted to prove that the intended users can identify the key functions of the device and to assess, that they can operate the device in a safe and effective manner based on their knowledge and following the directions for use in the device label.

The BEMER Therapy Systems usability study design follows FDA's human factors guidance for industry entitled, *Applying Human Factors and Usability Engineering to Medical Devices* (February 3, 2016). In summary, BEMER Therapy Systems, as labeled, are safe and effective in use by lay and professional users and therefore it is suitable for Over-The-Counter (OTC) use.

Substantial Equivalence:

The Bemer Therapy System is as safe and effective as its predicate device. BEMER therapy Systems have equivalent technology characteristics and similar principles of operation. The intended use is the same as its predicate device.

The differences between the BEMER Therapy Systems and its predicate device raise no new safety or effectiveness issues. Clinical performance data demonstrate that BEMER therapy Systems are as safe as the predicate device and it is suitable for Over-The-Counter (OTC).

Conclusion:

Summarized, all technical and performance data indicate that BEMER Therapy System are equivalent to the predicate device. Thus, BEMER Therapy Systems are substantially equivalent.