February 4, 2021

Bemer INT. AG
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K210174
Trade/Device Name: BEMER Classic Set and BEMER Pro-Set
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 21, 2021
Received: January 22, 2021

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210174

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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Date Prepared: 04-Feb-2021

I Submitter

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Submitter Contact: Sandra Schwarzenberger
Quality Director

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	BEMER Classic Set and BEMER Pro-Set
Common/Usual Name:	Powered Muscle Stimulator
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation	(21 CFR 890.5850)
Regulatory Class:	II
Product Code:	NGX

III Predicate Device: BEMER Classic Set and BEMER Pro-Set (K151834)

IV 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 systems improve local blood distribution via electromagnetic stimulatory principles. The indications for use allow application to increase local blood circulation or stimulate healthy muscles in order to improve and facilitate muscle performance.

The BEMER devices are noninvasive, fully reusable (no disposable components such as electrodes), and have configurations allowing both patient/home and professional/office use.

This submission is specifically requesting to add the applicators, B.BODY and B.SIT to the already cleared BEMER Therapy System.

The device contains firmware that controls the user interface. It also contains that controls the pulse generator, battery charger, audion and pushbutton controller.

V Indications for Use:

The BEMER therapy systemin indications for use as cleared under K151834, remain unchanged.

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

Environments of use: OTC (identical to K151834).

VI Comparison of Technological Characteristics and Performance with the Predicate

Table 1 below provides the summarized equivalence comparison of general intended uses/actions, specific indications for use, equivalence of key clinical and technical features between subject and predicate devices, along with a full listing of technical and conformance specifications.

Table 1: Comparison of Subject vs. Predicate

	BEMER Therapy Systems Applicator: B. BODY **Subject Device**	BEMER Therapy Systems Applicator: B.SIT **Subject Device**	BEMER Therapy Systems Applicator: B.PAD **Predicate Device K151834**	BEMER Therapy Systems Applicator: B.SPOT **Predicate Device K151834**
Classification Code(s)	Primary: Powered Muscle Stimulator NGX 890.5850	Primary: Powered Muscle Stimulator NGX 890.5850	Primary: Powered Muscle Stimulator NGX 890.5850	Primary: Powered Muscle Stimulator NGX 890.5850
Indications for Use	*The BEMER therapy is indicated:* • *To temporarily increase local blood circulation in healthy leg muscles.* • *To stimulate healthy muscles in order to improve and facilitate muscle performance.*	*The BEMER therapy is indicated:* • *To temporarily increase local blood circulation in healthy leg muscles.* • *To stimulate healthy muscles in order to improve and facilitate muscle performance*	*The BEMER therapy is indicated:* • *To temporarily increase local blood circulation in healthy leg muscles.* *To stimulate healthy muscles in order to improve and facilitate muscle performance.*	*The BEMER therapy is indicated:* • *To temporarily increase local blood circulation in healthy leg muscles.* • *To stimulate healthy muscles in order to improve and facilitate muscle performance.*

	BEMER Therapy Systems Applicator: B. BODY **Subject Device**	BEMER Therapy Systems Applicator: B.SIT **Subject Device**	BEMER Therapy Systems Applicator: B.PAD **Predicate Device K151834**	BEMER Therapy Systems Applicator: B.SPOT **Predicate Device K151834**
PRIMARY MODE OF ACTION	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via magnetic field induction
Treatment of large and/or multiple regions simultaneously	X	X	X	X
Enlarged	**B.BODY** Basic Plan Treatment Intensities: **1-6** Treatment time: **8 min** Lower extremities and upper torso	**B.SIT** Program settings P1-P3 Intensities: **1-10** Treatment time: **8-20min** Application module for local treatments.	**B.PAD** Program settings P1-P3 Intensities: **1-10** Treatment time: **8- 20min** Application module for local treatments.	**B.SPOT** Program settings P1-P3 Intensities: **1-10** Treatment time: **8- 20min** Application module for local treatments.
Local (**System Pro** can use 2 different applicators) (**System Classic** can use only two B. BODY`s)	Local applicator (max. 2 applicators) Local treatment skeletal muscles treatment area restricted by applicator geometry Intensities:**1-10** Treatment time: **8 -20min**	Local applicator Local treatment on skeletal muscles treatment area restricted by applicator geometry Intensities:**1-10** Treatment time: **8- 20min**	Local applicator (max. 2 applicators Local treatment on skeletal muscles treatment area restricted by applicator geometry Intensities: **1-10** Treatment time: **8-20min**	Local applicator (max. 2 applicators) Local treatment on skeletal muscles treatment area restricted by applicator geometry Intensities: **1-10** Treatment time: **8-20min**
Enlarged + Local	B. BODY plus local applicator (1 of each) Lower extremities and upper torso plus local application on skeletal muscles	B.SIT plus local applicator	B.PAD plus local applicator	B.SPOT plus local applicator
Model (System)	B.BOX Professional B.BOX Classic	B.BOX Professional B.BOX Classic	B.BOX Professional B.BOX Classic	B.BOX Professional B.BOX Classic
Weight	**System:** **1.3kg** (B.BOX Classic) **1.4kg** (B.BOX Professional) **Applicator:** **2 kg** (B. BODY Classic & Professional)	**System:** **1.3kg** (B.BOX Classic) **1.4kg** (B.BOX Professional) **Applicator:** **1.6 kg** (B. SIT	**System:** **1.3kg** (B.BOX Classic) **1.4kg** (B.BOX Professional) **Applicator:** **0.38kg** (B.PAD)	**System:** **1.3kg** (B.BOX Classic) **1.4kg** (B.BOX Professional) **Applicator:** **0.3kg** (B. SPOT)

	BEMER Therapy Systems Applicator: B. BODY **Subject Device**	BEMER Therapy Systems Applicator: B.SIT **Subject Device**	BEMER Therapy Systems Applicator: B.PAD **Predicate Device K151834**	BEMER Therapy Systems Applicator: B.SPOT **Predicate Device K151834**
Dimensions (Applicator)	B. BODY Classic & Professional **180 x 60 x 2 cm**	B.SIT **45 x 37 x 4 cm**	B.PAD **111 x 13 x 1,5 cm**	B. SPOT **13 x 13 x 3,0 cm**
Average Flux density (Applicator)	≈ 35 µT (max. level) *(B. BODY Classic & Professional)*	≈ 100 µT (max. level)	≈ 100 µT (max. level)	≈ 100 µT (max. level)
Average Flux density *plus* (Applicator)	≈ 50 µT (max. level) *(B. BODY Classic & Professional)*	≈ 150 µT (max. level)	≈ 150 µT (max. level)	≈ 150 µT (max. level)
Power Consumption (System)	30 Watt max.	30 Watt max.	30 Watt max.	30 Watt max.
Input (System)	100-240 VAC 50- 60 Hz, 0.6A	100-240 VAC 50- 60 Hz, 0.6A	100-240 VAC 50- 60 Hz, 0.6A	100-240 VAC 50- 60 Hz, 0.6A
Output (System)	12-15.1 VDC, 2.0 A Optional 7.2 V Li- Ion battery	12-15.1 VDC, 2.0 A Optional 7.2 V Li- Ion battery	12-15.1 VDC, 2.0 A Optional 7.2 V Li- Ion battery	12-15.1 VDC, 2.0 A Optional 7.2 V Li- Ion battery
Biocompatibility	Yes	Yes	Yes	Yes
Number of output modes (System)	1	1	1	1
Number of output channels and ports (System	2 for each	2 for each	2 for each	2 for each

Software / Firmware / Microprocessor controlled	Yes	Yes	Yes	Yes
Voltage / Current Level	1-10 intensity indicator	1-10 intensity indicator	1-10 intensity indicator	1-10 intensity indicator
Timer Range	8-20 minutes	8-20 minutes	8-20 minutes	8-20 minutes
Compliance with voluntary standards	IEC60601-1 IEC 60601-1-2 EN 60601-1-6 EN 62366 EN 60601-1-11	IEC60601-1 IEC 60601-1-2 EN 60601-1-6 EN 62366 EN 60601-1-11	IEC60601-1 IEC 60601-1-2 EN 60601-1-6 EN 62366 EN 60601-1-11	IEC60601-1 IEC 60601-1-2 EN 60601-1-6 EN 62366 EN 60601-1-11
Sterilization	Not provided sterile	Not provided sterile	Not provided sterile	Not provided sterile

VII Substantial Equivalence

The B.BODY and B.SIT applicators have the same indications for use as the predicate, K151834.

Intended Use/ Indications for Use
The B.BODY and B.SIT applicators can only be used with the predicate B/BOX, K151834. They are accessories to the predicate and therefore have the same indications for use, population and use environments as the predicate, K151834.

Technological Characteristics
The technology of the coils is identical to that of the predicate applicators. The output is the same or less as the predicate, K151834. Specific to the B.BODY applicator having lower power outputs, average flux density, relative to the other applicators as this applicator provides local stimulation of more superficial muscles to temporarily increase local blood flow. The other applicators are used for applications for deeper penetration and therefore are intended for a more targeted therapy.

Principles of Operation
The principle of operation is identical to the predicate, K151834.

Non-clinical Testing
Performance testing demonstrated that the subject applicators performed equivalent to the predicate applicators. Testing included:

Performance testing involved multiple measurements of:

- BEMER signal waveform current output (AC RMS in mA) generated from B.BOX Classic and Professional consoles as input to the applicators
- magnetic flux output (µT) generated from B.BODY, B.SPOT, B.SIT and B.PAD applicators at all signal intensity input levels 1-10

Software

- Unchanged

Electrical / EMC

- Unchanged but evaluated under
- IEC 60601-1 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 - Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- EN 60601-1-11 - 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
- EN 60601-1-6 - Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- EN 62366 - Medical devices — Part 1: Application of usability engineering to medical devices

Biocompatibility

- ISO 10993-5 - Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

Discussion of Differences

The differences between the proposed and predicate device are solely related to the addition of addition of the B.BODY and B.SIT accessories. The devices themselves are identical in hardware and software. Specific to the B.BODY applicator having lower power outputs, average flux density, relative to the other applicators as this applicator provides local stimulation of more superficial muscles to temporarily increase local blood flow. The other applicators are used for applications for deeper penetration and therefore are intended for a more targeted therapy.

These changes do not alter the indications for use, patient population, environments of use, technological characteristics, contraindications, or performance specifications. The differences do not raise new concerns of safety or effectiveness.

Substantial Equivalence Conclusion

The changes to this device do not alter the indications for use, patient population, environments of use, technological characteristics, contraindications, or performance specifications. The differences do not raise new concerns of safety or effectiveness.

BEMER International, AG has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device does not raise any new safety concerns compared to the predicates.