June 8, 2023

BEMER International AG
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K231368
Trade/Device Name: BEMER Therapy System Evo
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 11, 2023
Received: May 11, 2023

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director
THT5B3: 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)*
K231368

Device Name
BEMER Therapy System Evo

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.

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

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510(k) Summary

Date Prepared: 08-Jun-2023

I Submitter

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Phone: +423-792-7386

Submitter Contact: Sandra Schwarzenberger
Quality Director

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	BEMER Therapy Systems Evo
Common/Usual Name:	Powered Muscle Stimulator
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation	(21 CFR 890.5850)
Product Code:	NGX

III Predicate Device:

	BEMER Classic Set and BEMER Pro-Set (K151834)
Common/Usual Name:	Powered Muscle Stimulator
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation	(21 CFR 890.5850)
Product Code:	NGX

Secondary Predicate Device:

	BEMER Classic Set and BEMER Pro-Set (K210174)
	B. Sit and B. Body applicators
Common/Usual Name:	Powered Muscle Stimulator
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation	(21 CFR 890.5850)
Product Code:	NGX

IV Device Description:

BEMER therapy system Evo is a noninvasive physical medicine device that can be used as a supportive therapy to increase local blood circulation.

BEMER Therapy System Evo improves 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 device is noninvasive, fully reusable (no disposable components such as electrodes), and has configurations allowing both patient/home and professional/office use.

This submission is for the redesigned BEMER Therapy System Evo model including all previous applicators plus a new applicator, B.BED Evo.

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

V Indications for Use:

- 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 System Evo **Subject Device**	BEMER Therapy Systems **Predicate Device K151834**	BEMER Therapy Systems Applicator: B.SIT and B.BODY **Secondary Predicate K210174**
Classification Code(s)	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 System Evo 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 System 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 System is indicated: To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance.
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
Treat large and/or multiple regions Simultaneously	Yes B. Spot Evo and B. Pad Evo B. Grip Evo – holds B. Spot B. Sit Evo Application modules for local treatments. Local treatment on skeletal muscles. Treatment area restricted by applicator geometry. B. Body Evo and B. Bed Evo Lower extremities and upper torso. Local treatment on skeletal muscles. Treatment area restricted by	Yes B. Spot and B. Pad B. Grip – holds B. Spot Application modules for local treatments. Local treatment on skeletal muscles. Treatment area restricted by applicator geometry.	Yes B. Sit Application module for local treatments. Local treatment on skeletal muscles. Treatment area restricted by applicator geometry. B. Body – Lower extremities and upper torso. Local treatment on skeletal muscles. Treatment area restricted by applicator geometry

	BEMER Therapy System Evo **Subject Device**	BEMER Therapy Systems **Predicate Device K151834**	BEMER Therapy Systems Applicator: B.SIT and B.BODY **Secondary Predicate K210174**
	applicator geometry.		
Multiple Applicators	B. Spot Evo B. Pad Evo B. Grip Evo B. Sit Evo B. Body Evo B. Bed Evo (new)	B. Spot B. Pad B. Grip	B. Sit B. Body
Average Flux density (Applicator)	≈ 35 µT to 50 µT (max. level) B. Body Evo and B. Bed Evo ≈ 100 to 150 µT (max. level) B. Sit Evo, B. Pad Evo, B. Grip Evo and B.Spot Evo	≈ 100 to 150 µT (max. level) B. Pad, B. Grip and B.Spot	≈ 35 µT to 50 µT (max. level) B. Body ≈ 100 to 150 µT (max. level) B. Sit
Power Consumption (System)	30 Watt max.	30 Watt max.	30 Watt max.
Number of output modes (System)	1	1	1
Number of output channels and ports (System	2 for each	2 for each	2 for each
Voltage / Current Level	1-3 intensity indicator	1-10 intensity indicator	1-10 intensity indicator
Timer Range	8-20 minutes	8-20 minutes	8-20 minutes
Biocompatibility	Surface Contact, Intact skin, permanent duration of use (> 30 days) ISO 10993-5:2009 ISO 10993-10:2010	Surface Contact, Intact skin, permanent duration of use (> 30 days)	Surface Contact, Intact skin, permanent duration of use (> 30 days)
Compliance with voluntary standards	IEC 60601-1 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

VII Substantial Equivalence

Intended Use/ Indications for Use
The BEMER Therapy System Evo and its applicators have the same indications for use as the predicates, K151834 and K210174.

Technological Characteristics
The technology of the coils is identical to that of the predicate applicators. The coils of the B.Body Evo and B.Bed Evo have been redesigned but treat the same regions with the identical power out as the predicates, K151834 and K210174. Specific to the B.Bed Evo applicator has the same power outputs, average flux density, as the cleared B. Body Evo, K210174. It provides local stimulation of more superficial muscles to temporarily increase local blood flow while 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 Evo console as input to the applicators
- Magnetic flux output (μT) generated from B.BODY Evo, B.SPOT Evo, B.SIT Evi, B.BED Evo and B.PAD Evo applicators at all signal intensity input levels

Software

- Validation and Verification performed.

Electrical / EMC

- 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

- Surface Contact, Intact Skin, Permanent duration of use. Evaluated with ISO 10993-5 – 2009 - Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity and ISO 10993-10 – 2010 - 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:

- Updating the console, B.Box Evo to a new look
- Change in coil design for the B. Body Evo from a 6 coil to a 16 coil configuration. Output is the same as the predicate B. Body, K210174
- Adding B. Bed Evo applicator which is a larger configuration of B. Body with the same 16 coil configuration and outputs.
- Limiting the intensity settings to 3 vs. 10 as in the predicate

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 different 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 different 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 different safety concerns compared to the predicates, and is therefore substantially equivalent to the predicate devices.