February 19, 2021

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Regulatory Consultant
Quality and Regulatory Services
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K203488
Trade/Device Name: emField
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: November 24, 2020
Received: November 27, 2020

Dear Scott Blood:

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,

Patrick Antkowiak, PhD
Assistant Director (acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203488

Device Name
emField

Indications for Use *(Describe)*
The emField is indicated to be used for:

*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; and
*Maintaining or increasing range of motion.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
emField

1. Basic Information-Submitter:

510(k) Owner:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm Germany Establishment Registration: 8010720
Official Contact:	Mrs. Ute Hauss Manager Regulatory Affairs Phone: +49-731-9761-216 Fax: +49-731-9761-118 E-mail: u.hauss@zimmer.de

Date Summary Prepared:	November 24, 2020

2. Device Name:

Trade Name:	emField
Common Name:	Powered Muscle Stimulator
Classification Name:	Stimulator, Muscle, Powered
Regulation Number:	21 CFR 890.5850
Product Code:	IPF
Classification:	Class II

3. Predciate Device:	HPM-6000 – K160992
Company Name:	BTL Industries, Inc.
Reference Device:	emFieldPro – K182963
Company Name:	Zimmer MedizinSysteme GmbH

4. Device Description:

emField is a non-invasive therapeutic device. The device produces a magnetic field that interacts with the tissues of the human body. By muscle stimulation, the emField is indicated for bulk muscle excitation in the legs or arms for rehabilitative purposes.

The device housing protects the patient from electrical shock and mechanical injuries. The device is mobile standalone equipment with four wheels. Two applicators are available for therapy: a large and a small one. The main body of emField is used to control function of magnetic stimulation. It is operated with parameters such as

Frequency, Time and Intensity. These parameters can be controlled by the user on LCD and with the help of a rotary knob at the user control panel.

Indications for Use Statement:

emField is indicated to be used for:

- 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; and
- Maintaining or increasing range of motion.

ATTRIBUTE	SUBJECT DEVICE Zimmer MedizinSysteme GmbH emField This Submission	PREDICATE DEVICE BTL Industries, Inc. HPM-6000 K160992	REFERENCE DEVICE Zimmer MedizinSysteme GmbH emFieldPro K182963
Intended Use	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 NGX– Stimulator, Muscle, Powered, For Muscle Conditioning
	The emField is indicated to be used for: • 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; and • Maintaining or increasing range of motion.	The HPM-6000 is indicated to be used for: • 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; and • Maintaining or increasing range of motion.	The emFieldPro is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.

The Indications for Use statement for emField is identical to the predicate device. The Indications for Use is not the same for the reference device, however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for conditioning and stimulation of muscles.

5. Technological Characteristics:

The emField device has the equivalent technology and principles of operation as its predicate device. The emField device and its predicate are comprised of a system console and applicators. The system console consists of the electromagnetic field generators, computer, and the touch-screen control panel. The emField is equipment that generates a magnetic field by applying a strong current to an applicator. The technical characteristics of the emField and its predicate device, are equivalent.

Technological Characteristic	**SUBJECT DEVICE Zimmer MedizinSysteme GmbH emField This Submission**	**PREDICATE DEVCIE BTL Industries, Inc. HPM-6000 K160992**	**REFERENCE DEVICE Zimmer MedizinSysteme GmbH emFieldPro K182963**
Primary Function	Muscle stimulation	Muscle stimulation	Muscle stimulation
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction
Electrical Protection	Class I, BF	Class II, BF	Class I, BF
User Interface	Touch screen	Touch screen	Touch screen
Touch screen size	7”	8.4’’	7’’
Type of Energy	Magnetic field	Magnetic field	Magnetic field
Number of Applicators	2	2	2
Number of Magnetic Coils in the Applicator	1	1	1
Magnetic Field Intensity	Large applicator: 0.5 – 1.5 T +/-20% Small applicator: 0.5 – 2.0 T +/-20%	299-1 applicator: 0.5 – 1.8 T 299-2 applicator: 0.7 – 2.5 T	Large applicator: 0.5 – 1.5 T +/-20% Small applicator: 0.5 – 2.0 T +/-20%
Total Induced Current in Tissue (mA)	251	unknown	251
Type of Operation	Continuous	Continuous	Continuous

Technological Characteristic	SUBJECT DEVICE Zimmer MedizinSysteme GmbH emField This Submission	PREDICATE DEVCIE BTL Industries, Inc. HPM-6000 K160992	REFERENCE DEVICE Zimmer MedizinSysteme GmbH emFieldPro K182963
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz
Pulse Duration	Large applicator: 400 µs +/- 20% Small applicator: 250 µs +/- 20%	280 +/- 20% µs	Large applicator: 400 µs +/- 20% Small applicator: 250 µs +/- 20%
Pulse Amplitude	0 – 100 %	0 – 100 %	0 – 100 %
Selection of parameters (Intensity, Time)	Yes	unknown	Yes
Therapy Time	Up to 60 min	Up to 60 min	Up to 60 min
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Sine, biphasic	Symmetrical Biphasic Sine Wave
Energy Source	100–240 V AC, 50-60 Hz, max 12.5 A	100–240 V AC, 50–60 Hz, max. 14 A	100–240 V AC, 50–60 Hz, max 12.5 A
System Dimensions (WxHxD)	542 x 501 x 993 mm	500 × 970 × 580 mm (20×38×23 in)	542 x 501 x 993 mm
Operating Ambient Temperature	10° C to 30° C	10° C to 30° C	10° C to 30° C
Operating Ambient Humidity	30-85%	30-75%	30-85%
Weight	Approx. 60 kg	33 kg	Approx. 60 kg
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only

There are no technological differences between the emField device and the reference device, as they are the same device. There are few differences between the technological differences of the subject device and those of the predicate device. Those differences have been discussed and do not affect device safety or performance. The subject device has all features of the predicate device. emField does not raise any new types of safety or effectiveness questions.

The Zimmer MedizinSysteme GmbH emField has the same technological characteristics as the predicate device.

6. Performance data

The emField device has been investigated and tested against and complies with the following voluntary standards:

Standards	Standards Organization	Standards Title
60601-1	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-1-6	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
60601-2-10	IEC	Medical electrical equipment – Part 2-10: Particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators
62366-1	IEC	Medical devices – Application of usability engineering to medical devices
62304	IEC	Medical devices software –software life cycle processes
14971	ISO	Medical devices – Application of risk management to medical devices

The following table shows a comparison of the performance testing in comparison to the predicate devices:

Standards	**SUBJECT DEVICE** **Zimmer MedizinSyteme GmbH** **emField** **This Submission**	**PREDCIATE DEVICE** **BTL Industries, Inc.** **HPM-6000** **K160992**	**REFERENCE DEVICE** **Zimmer MedizinSyteme GmbH** **emFieldPro** **K182963**
IEC 60601-1	X	X	X
IEC 60601-1-2	X	X	X
IEC 60601-2-10	X	X	X

Standards	SUBJECT DEVICE Zimmer MedizinSyteme GmbH emField This Submission	PREDCIATE DEVICE BTL Industries, Inc. HPM-6000 K160992	REFERENCE DEVICE Zimmer MedizinSyteme GmbH emFieldPro K182963
ISO 10993-1 ISO 10993-5 ISO 10933-10	Not applicable (no patient-contacting materials)	X	Not applicable (no patient-contacting materials)

According to this comparison table all required performance tests were conducted and show substantial equivalence with the predicate devices.

Preclinical Testing Results

The following tests were performed on the subject device in addition to the testing listed above:

- Magnetic Field testing
- Tissue Heating study
- Usability testing

The testing above confirmed that the large and small applicator each operate within the magnetic field intensity specifications for each applicator and that the tissue being treated by the device does not present an appreciable rise in temperature at maximum intensity to cause a risk to the patient.

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

7. 510(k) Summary:

Zimmer MedizinSysteme GmbH has demonstrated that the emField device is substantially equivalent to the predicate device and reference device.