October 5, 2023

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

Re: K230780
Trade/Device Name: MFG-05
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: August 31, 2023
Received: September 5, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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General Hospital and Urology 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)*
K230780

Device Name
MFG-05

Indications for Use *(Describe)*

MFG-05 is intended to provide entirely non-invasive electromagnetic stimulation of the pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.

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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510(k) Summary
MFG-05

1. Basic Information-Submitter:

510(k) Owner: Zimmer MedizinSysteme GmbH
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Date Summary Prepared: October 5, 2023

2. Device Name:

Trade Name:	MFG-05
Common Name:	Stimulator, Electrical, Non-implantable, For Incontinence
Regulation Name:	Nonimplanted electrical continence device
Regulation Number:	21 CFR 876.5320
Product Code:	KPI
Classification:	Class II

3. Predicate Devices: HPM-6000UF – K181497
Company Name: BTL Industries, Inc.
The predicate has not been subject to a design-related recall

Reference Device: emField – K203488
Company Name: Zimmer MedizinSysteme GmbH

4. Device Description:

The MFG-05 is a non-invasive therapeutic device. The device produces a magnetic field that interacts with the tissues of the human body. By stimulation of the pelvic floor musculature, the MFG-05 helps to treat of male and female urinary incontinence.

The device housing protects the patient from electrical shock and mechanical injuries. The device is a mobile standalone equipment with four wheels. One applicator is available for therapy and is positioned centrally under the pelvic floor of the patient while the patient is wearing sport pants or any other pants without metallic parts. The device is for prescription use and used by a trained medical professional in a professional healthcare facility. The main body of MFG-05 is used to control the function of magnetic stimulation. It is operated with parameters such as frequency, time and intensity. These parameters can be controlled by the user on screen display and with the help of a rotary knob at the user control panel.

Indications for Use Statement:

MFG-05 is intended to provide entirely non-invasive electromagnetic stimulation of the pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.

ATTRIBUTE	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH MFG-05 **This Submission**	**PREDICATE DEVICE** BTL Industries, Inc. HPM-6000UF K181497	**REFERENCE DEVICE** Zimmer MedizinSysteme GmbH emField K203488
Intended Use	MFG-05 is intended to provide entirely non-invasive electromagnetic stimulation of the pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.	HPM-6000UF is intended to provide entirely non-invasive electromagnetic stimulation of the pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.	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 Indications for Use statement of MFG-05 is identical to that of the predicate device.

5. Technological Characteristics:

The MFG-05 device has similar technological characteristics and principles of operation as its predicate device. The MFG-05 device and its predicate device are comprised of a system console and one applicator. The system console consists of electromagnetic field generators, a computer and the touch-screen control panel. The technological similarities and differences between the subject device and the predicate device are described below in the comparison table

The MFG-05 device was developed based on the reference device (emField) and has equivalent technology and principles of operation as the reference device. The emField device allows the use of one large applicator or one small applicator to be used only one at a time. The MFG-05 has the small applicator removed. The MFG-05 and its reference device generate both a magnetic field by applying a strong current to an applicator. The subject device has all features of the reference device.

The technological characteristics of the MFG-05 does not raise any different questions of safety or effectiveness.

Technological Characteristics	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH MFG-05 **This Submission**	**PREDICATE DEVICE** BTL Industries, Inc. HPM-6000UF K181497	**REFERENCE DEVICE** Zimmer MedizinSysteme GmbH emField K203488
Clinical Use	Prescription Use	Prescription Use	Prescription Use
Applicable Patients	Male and Female, Adults only	Male and Female, Adults only	Adults only
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
Type of Energy	Magnetic field	Magnetic field	Magnetic field
Energy Source	100 - 120 V AC, 50/60 Hz, max. 2.7 kVA; 220 - 240 V AC, 50/60Hz, max. 2.7 kVA	100 – 240 V AC, 50 - 60 Hz, max 14 A	100-240 V AC, 50-60 Hz, max 12.5 A
Number of output channels	1	1	2
Magnetic Field Intensity	Applicator: 0.5 – 1.5 T +/-20%	0.7 – 2.5 T	Large applicator: 0.5 – 1.5 T +/-20% Small applicator: 0.5 – 2.0 T +/-20%
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz

Technological Characteristics	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH MFG-05 **This Submission**	**PREDICATE DEVICE** BTL Industries, Inc. HPM-6000UF K181497	**REFERENCE DEVICE** Zimmer MedizinSysteme GmbH emField K203488
Pulse Width	400 µs (+/- 20%)	280 µs (+/- 20%)	Large applicator: 400 µs +/- 20% Small applicator: 250 µs +/- 20%
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Dual phase, rectangular pulses	Symmetrical Biphasic Sine Wave
Therapy Time	Up to 60 min	Up to 60 min	Up to 60 min
Interface	Touchscreen	Touchscreen	Touchscreen
Firmware controlled	Yes	Yes	Yes
Software Level of Concern	Moderate	Moderate	Moderate
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only
Feedback	By patient	By patient	By patient
Operating Temperature	10° C to 30° C (50° F to 86° F)	+10° C to +30° C (50° F to 86°F)	10° C to 30° C
Main Unit Dimensions (WxHxD)	455x1000x417 mm	500×970×580 mm (20×38×23 in)	542x501x993 mm
Applicator Dimensions (WxHxD)	170x48x402 mm	730x730x730 mm (29x29x29 in)	161x41.5x300.5 mm
System Weight	Approx. 60 kg (No Safe Working Load)	46 kg (101 lb)	Approx. 60 kg

There are a few technological differences between the subject device and the predicate device, including differences in stimulation waveform parameters (i.e., magnetic field intensity, pulse width) and main unit dimensions. Performance testing were provided to demonstrate that these different do not affect the safety or performance of the device as compared to the predicate device.

6. Performance data

The MFG-05 has been investigated and tested against and complies with the following voluntary standards:

Standards	Standards Organization	Standards Title
ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text)	ANSI/AAMI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2 Edition 4.1 2020-09	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 Edition 3.1 2013-10	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
60601-2-10 Edition 2.1 2016-04	IEC	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
62366-1 Edition 1.0 2015-02	IEC	Medical devices - Part 1: Application of usability engineering to medical devices
62304 Edition 1.1 2015-06	IEC	Medical devices software –software life cycle processes
14971 Third Edition 2019-12	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 device:

Standards	**SUBJECT DEVICE** Zimmer MedizinSyteme GmbH MFG-05 **This Submission**	**PREDICATE DEVICE** BTL Industries, Inc. HPM-6000UF K181497
ANSI/AAMI ES60601-1	X	X
IEC 60601-1-2	X	X
IEC 60601-2-10	X	X
ISO 10993-1 ISO 10993-5 ISO 10933-10	Not applicable (no patient-contacting materials)	X

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

Preclinical Testing Results

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

- Performance testing per IEC 60601-2-10
- Magnetic Field testing
- SAR analysis and Tissue Heating study

The testing above confirmed that the applicator operates within the magnetic field intensity specifications 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. Conclusion:

There are no differences with respect to the indications for use and many of the technological characteristics between the MFG-05 and the predicate device. The minor differences mentioned above do not raise new questions of safety or effectiveness. The performance testing provided supports that the MFG-05 is as safe and effective as the predicate device, and therefore is substantially equivalent.