November 15, 2019

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

Re: K192940
Trade/Device Name: CoolTone
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 17, 2019
Received: October 18, 2019

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,

For Vivek Pinto, Ph.D.
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)*

K192940

Device Name
CoolTone

Indications for Use *(Describe)*

CoolTone is indicated to be used for:
•Improvement of abdominal tone, strengthening of the abdominal muscles, development for firmer abdomen.
•Strengthening, Toning and Firming of buttocks and thighs.

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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5. 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Establishment Registration: 8010720

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DATE PREPARED: October 17, 2019

II. DEVICE:

TRADE NAME: CoolTone

COMMON NAME: Powered Muscle Stimulator

CLASSIFICATION NAME: Stimulator, Muscle, Powered, For Muscle Conditioning

DEVICE CLASSIFICATION: Class II, 21 CFR §890.5850

PRODUCT CODE: NGX

III. PREDICATE DEVICE: emFieldPro (K182963)

IV. DEVICE DESCRIPTION:

The CoolTone is a non-invasive therapeutic device. The device produces an electromagnetic field that interacts with the tissues of the human body. By muscle stimulation, the CoolTone helps to strengthen, tone and firm abdomen, buttocks and thighs.

The device housing protects the patient from electrical shock and mechanical injuries. The device is a mobile standalone equipment with four wheels.

Two large applicators are connected to the control unit and can be used simultaneously depending on the treatment. The device is a medical equipment that generates a magnetic

field by applying a strong current to an applicator. The CoolTone is equipped with the securement system which is designed to maintain applicator position throughout treatment.

A large color touch screen facilitates the use of the device. The on-screen information guides the user step-by-step through the entire treatment process. The treatment is operated through parameters such as frequency, time and intensity. Three pre-set treatment options are available for users to choose from: Abdomen, buttocks and thighs.

V: INDICATION FOR USE:

CoolTone is indicated to be used for:

- Improvement of abdominal tone, strengthening of the abdominal muscles, development for firmer abdomen.
- Strengthening, Toning and Firming of buttocks and thighs.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The technological characteristics and operating principal associated with the treatment remain unchanged from the predicate device. The device produces electromagnetic field that interacts with the tissues of the human body.

Changes were made to the predicate's (K182963) system hardware and the software to allow the modified system to be able to use up to two large applicators at the same time. The applicator design, size and shape are unchanged. The applicator connection to the control unit is now detachable.

The technological similarities and differences between the subject device and the predicate device are described below in the comparison table. The differences do not raise any new types of safety or effectiveness questions.

Table 1: Technological Similarities between Proposed and Predicate Device

Technological Characteristics	**SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone**	**PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)**
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 NGX – Stimulator Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 NGX – Stimulator Muscle, Powered, Muscle Conditioning

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone	PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)
Indications for Use	The CoolTone 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 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.
Primary Function	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
Electrical Protection	Class I, BF	Class I, BF
User Interface	Touch screen	Touch screen
Touch screen size	12”	7”
Positioning of Applicator	Securement system	Arm
Firmware Controlled	Yes	Yes
Type of Energy	Magnetic field	Magnetic field
Magnetic Field Intensity	Large applicator 0.5 – 1.35T +/- 20%	Large applicator 0.5 – 1.5T +/- 20% Small applicator 0.5 – 2.0T+/- 20%
Number of outputs	2	2
Number of Magnetic Coils in the Applicator	1	1
Number of applicators	Up to two large applicators can be operational at same time	One large and one small applicator, operational one applicator at a time
Applicator connection	Detachable from the control unit	Fixed to the control unit
Total Induced Current in Tissue (mA)	327	251
Type of Operation	Continuous	Continuous
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz
Pulse Duration	Large applicator 370 µs +/- 20%	Small applicator: 250us +/- 20% Large applicator: 400us +/- 20%

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone	PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)
Pulse Amplitude	0 – 100 %	0 – 100 %
Selection of parameters (Intensity, Time)	Yes	Yes
Treatment Time	Up to 30 min	Up to 60 min
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave
Energy Source	220-240VAC, 50-60 Hz	100 – 240 V AC, 50–60 Hz
System Dimensions (WxHxD)	600 x 1100x 600 mm	501x993x542mm
Operating Ambient Temperature	10°C to 28 °C	10°C to 30°C
Environmental Specifications	For indoor use only	For indoor use only

Table 2: **Technological Similarities between Proposed and Predicate Device per FDA Guidance for Industry for Powered Muscle Stimulators for 510(k)s (June 9, 1999)**

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone	PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)	Comments
4. Power Source(s) - Method of Line Current Isolation - Patient Leakage Current Normal condition Single fault condition	60601 compliant < 1 µA 3.9 µA	60601 compliant 1 µA 3 µA	60601 Compliant
5. Number of Output Modes	1	1	
6. Number of Output Channels - Synchronous or Alternating? - Method of Channel Isolation	2 Synchronous N/A	2 Alternating N/A	No electrodes - applicators are not connected to patient

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone	PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)	Comments
7. Regulated Current or Regulated Voltage?	Voltage	Voltage	Controlled voltage to the coil
8. Software/Firmware/Microprocessor Control?	Yes	Yes	
9. Automatic Overload Trip?	N/A	N/A	No electrodes - applicators are not connected to patient
10. Automatic No-Load Trip?	N/A	N/A	No electrodes - applicators are not connected to patient
11. Automatic Shut Off?	Yes	Yes	Unit shuts off with specified timer
12. Patient Override Control?	No	No	Treatment is delivered by health care provider
13. Indicator Display: - On/Off Status? - Low Battery? - Voltage/Current Level?	 Yes N/A No	 Yes N/A No	
14. Timer Range (minutes)	Up to 30 Min	Up to 60 Min	
15. Compliance with Voluntary Standards?	N/A	N/A	
16. Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes	Yes	
17. Weight	80 Kg	60 Kg	

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone	PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)	Comments
19. Housing Materials and Construction	Steel and Injection Molded Plastics	Steel and Injection Molded Plastics	
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	
Shape (e.g., rectangular, spike, rectified sinusoidal)	Sinusoidal	Sinusoidal	
Maximum Output Voltage (specify units)	N/A	N/A	No electrodes - applicators are not connected to patient
Maximum Output Current (specify units)	N/A	N/A	No electrodes - applicators are not connected to patient
Pulse Width (specify units)	370 µs +/- 20%	250-400 µs +/- 20%	
Frequency (Hz)	1-150 Hz	1-150 Hz	
For interferential modes only: - Beat Frequency (Hz)	N/A	N/A	
For multiphasic waveforms only: - Symmetrical phases?	Yes	Yes	Biphasic
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	370 µs +/- 20%	250-400 µs +/- 20%	
Net Charge (mC per pulse) (If zero, state method of achieving zero net charge.)	N/A	N/A	No electrodes – applicators not connected to the patient
Maximum Phase Charge, (mC)	N/A	N/A	No electrodes – applicators not

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone	PREDICATE DEVICE Zimmer MedizinSyteme GmbH emFieldPro (K182963)	Comments
			connected to the patient
Maximum Current Density, (mA/cm^2)	N/A	N/A	No electrodes – applicators not connected to the patient – see SAR report
Maximum Power Density, (W/cm^2)(using smallest electrode conductive surface area)	N/A	N/A	No electrodes – applicators not connected to the patient
Burst Mode7 (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	N/A	N/A	
ON Time (seconds)	N/A	N/A	
OFF Time (seconds)	N/A	N/A	
Additional Features (if applicable)	N/A	N/A	

Substantial Equivalence Determination

a. Intended Use: There is no change to the indications for use for this submission between the Proposed and Predicate devices
b. Technological Characteristics

The CoolTone has the same technological characteristics as the predicate device (K182963) except for the following:

Technological Characteristics	Characteristic difference between CoolTone and Predicate Device	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Touch Screen Size	12” versus 7”	The size of the touch screen does not impact the icons and data visibly displayed on the screen.
Positioning of the applicator	Securement system versus arm	The securement system ensures applicator position during treatment. Biocompatibility testing was performed on the securement system since it may have patient contact. Please refer to Section 13.
Pulse Duration	370 µs +/- 20% versus 400 µs +/- 20%	No impact. The pulse width of the CoolTone device and the predicate device are in the typical clinical range of 50 to 500µs. Reference: “The effect of stimulus current pulse width on nerve fiber size recruitment patterns” by Robert B. Szlavik and Hubert de Bruin
Number of applicators	Up to two large applicators can be operational at same time versus one applicator at a time	The performance testing confirmed that the two applicators, either operated separately or simultaneously, performed within the magnetic field intensity of 0.5 – 1.35T +/- 20% 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. Please refer to Section 13.
Applicator connection	Detachable versus fixed	No impact. Each applicator can be detached from the control unit by a connector, for ease of service. Performance testing shows that the connector does not influence effectiveness of the treatment parameters.
Treatment time	Up to 30 minutes (CoolTone) versus 60 minutes (emField Pro)	No impact. A typical treatment session is 20 – 30 minutes.
System Dimensions (WxHxD)	600 x 1100 x 600 mm versus 501 x 993 x 542mm	Different dimensions have no influence on the safety or effectiveness of the device.
Energy Source	220-240VAC, 50-60 Hz versus 100 – 240 V AC, 50–60 Hz	No impact. The energy source is sufficient to operate the device under normal operating conditions.

Maximum Magnetic Field Intensity at Applicator Center Surface	Up to two Large applicators with 0.5 – 1.35T +/- 20% versus one large applicator with 0.5 – 1.5T +/- 20% and one small applicator 0.5 – 2.0T.	EMF is measured as 1.43T. The performance testing confirmed that the two applicators, either operated separately or simultaneously, performed within the magnetic field intensity of 0.5 – 1.35T +/- 20% 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.
Operating Ambient Temperature	10°C to 28 °C versus 10°C to 30°C	Lower ambient temperatures is preferred to facilitate applicator cooling. No impact is expected as a typical medical office sets room temperature to no higher than 27°C (80°F)

Any differences in their technological characteristics are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness. The CoolTone is substantially equivalent to the predicate K182963.

VII. PERFORMANCE DATA:

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

Standards	Standards Organization	Standards Title
60601-1:2005 + CORR: 1:2006 + CORR. 2:2007 + A1:2012 (Edition 3.1)	ANSI AAMI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2:2014 (Edition 4.0)	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-2-10:2016 (Edition 2.1)	IEC	Medical electrical equipment – Part 2-10: Particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators

Standards	Standards Organization	Standards Title
62366-1:2015 (Edition 1.0)	IEC	Medical devices – Application of usability engineering to medical devices
62304:2015 (Edition 1.1)	IEC	Medical devices software –software life cycle processes
10993-5: 2009	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10993-10: 2010	ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software Verification and Validation Testing

The software for the CoolTone has been updated, which includes an updated system and software architecture. The update allows CoolTone the ability to treat patients with up to two applicators simultaneously. The updated software also includes improved graphical user interface that sets treatment parameters by body region with an improved user flow.

The verification of the software requirements was performed in three steps: the verification of the software requirements, the verification of the design specifications and the verification of the software architecture. All the tests including Integration Tests (Tests of the System Architecture and the Design Specification) and the System Level Test (Test of functional requirements, that were tested in the software requirements verification) were performed successfully and met their acceptance criteria.

Biocompatibility Testing

The CoolTone includes a new securement system which is used to maintain applicator position throughout the treatment. The securement system is composed of two applicator covers, a strap, and a connection piece. The materials for these components have undergone biocompatibility testing. The system complies with ISO 10993-5: 2009, and ISO 10993-10: 2010.

Electrical safety and electromagnetic compatibility (EMC)

The device has undergone electrical and mechanical safety performance testing and electromagnetic compatibility testing as a result of the changes referenced. The system complies with IEC 60601-1:2005 + CORR: 1:2006 + CORR. 2:2007 + A1:2012 (Edition 3.1), and IEC 60601-1-2:2014 (Fourth Edition).

Essential Performance Testing

The testing above confirmed that the two applicators, either operated separately or simultaneously, performed within the magnetic field intensity of 0.5 – 1.35T +/- 20% 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.

Clinical Study

No clinical testing was required for this change.

VIII. CONCLUSION:

The Indication for Use for the CoolTone is the same as the device cleared in K182963. The changes that have been made to the system's hardware and software, along with the new feature to use two large applicators simultaneously as an option, do not affect the intended use, performance or risk profile of the device. The CoolTone system is substantially equivalent to the predicate device.