April 1, 2022

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

Re: K220601
Trade/Device Name: CoolTone
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 1, 2022
Received: March 2, 2022

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,

Heather Dean, PhD
Assistant Director
THT5B3: Acute Injury Devices
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)*
K220601

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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6. 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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DATE PREPARED: March 31, 2022

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: CoolTone (K192940)

IV. DEVICE DESCRIPTION:

The CoolTone system 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 the abdomen, buttocks and thighs.

The device is a mobile, standalone unit with four wheels and the control unit housing protects the patient from electrical shock and mechanical injury.. These features are unchanged.

Two large applicators are connected to the control unit and can be used simultaneously depending on the treatment. CoolTone is a medical device that generates a magnetic field by applying a strong current to an applicator. It is equipped with the securement system, designed to maintain the position of the applicator 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 variable parameters such as frequency, time and intensity. Three, pre-set treatment options are available for users to choose from: Abdomen, buttocks and thighs. These features are unchanged.

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 principles associated with the treatment remain unchanged from the predicate device. The subject device is identical to the primary predicate device, the CoolTone system, as cleared under K192940.

In comparison with the predicate device, the following changes have been made on the subject device:

Hardware: Control unit:

- A compressor cooler was added to the cooling circuit to enhance cooling performance;
- The single diode was replaced by a double diode on the capacitor stage to reduce the potential for treatment interruption;
- Foam tape was added to the compressor module to reduce noise;

Applicator:

- Design and manufacture process improvement was made to the applicator to prevent cracking and the leaking of coolant fluid;

Software：

- Modified to allow customers limited access to a device check and an advanced customer screen to facilitate troubleshooting;

- Implemented a treatment protocol that was within the previously cleared range of software specification;
- Adjusted the coolant flow, implemented relax-sequences and extended cooldown to reduce the potential interruption of treatment incurred by applicator warmth;
- Optimized pulsing sequence to reduce noise;

Labeling:

- The user's manual was updated to capture information obtained in post-market surveillance activity.

The technological characteristics of the subject device, as outlined in the comparison table below, remain the same as those of the predicate device.

Table 6.1: Technological Characteristics between Subject and Predicate Device

Device Name	Predicate Device CoolTone K192940	Subject Device CoolTone
Company Name	Zimmer MedizinSysteme GmbH	Same
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 NGX-Stimulator, Muscle, Powered, Muscle Conditioning	Same
Intended Use	• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	Same
Principle of Action	Initiating action potential of nerves results in muscle contraction	Same
Clinical Use	Prescription use	Same
Electrical Protection	Class I, BF	Same
User Interface	Touch screen, 12''	Same
Firmware Controlled	Yes	Same
Type of Energy	Magnetic field	Same
Number of outputs	2	Same
Number of Applicators	Up to two applicators can be operational at same time	Same
Applicator Connection	Detachable from the control unit	Same
Total Induced Current in Tissue (mA)	327	Same
Type of Operation	Continuous	Same
Number of Magnetic Coils in the Applicator	1	Same
Positioning of Applicator	Securement system	Same
Magnetic Field Intensity	0.5-1.35T ± 20%	Same
Pulse Repetition Rate	1 – 150 Hz	Same
Pulse Duration	370 µs ± 20%	Same
Pulse Amplitude	0 – 100%	Same

Device Name	Predicate Device CoolTone K192940	Subject Device CoolTone
Selection of parameters (Intensity, Time)	Yes	Same
Therapy Time	Up to 30 min	Same
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Same
Energy Source	220-240V, 50/60 Hz	Same
System Dimensions (WxHxD)	600x1100x600 mm	Same
Operating Ambient Temperature	10°C – 28 °C	Same
Environmental Specifications	For indoor use only	Same

Table 6.2: Technological Similarities between Proposed and Predicate Device per FDA Guidance for Industry for Powered Muscle Stimulators for 510(k)s (June 9, 1999)

Technological Characteristics	Predicate Device CoolTone K192940	Subject Device CoolTone	Comments
Power Source(s) - Method of Line Current Isolation - Patient Leakage Current Normal condition Single fault condition	60601 compliant < 1 µA 3.9 µA	Same	60601 Compliant
Number of Output Modes	1	Same	
Number of Output Channels - Synchronous or Alternating? - Method of Channel Isolation	2 Synchronous N/A	Same	No electrodes - applicators are not connected to patient
Regulated Current or Regulated Voltage?	Voltage	Same	Controlled voltage to the coil
Software/Firmware/ Microprocessor Control?	Yes	Same	
Automatic Overload Trip?	N/A	N/A	No electrodes - applicators are not connected to patient
Automatic No-Load Trip?	N/A	N/A	No electrodes - applicators are not connected to patient

Technological Characteristics	Predicate Device CoolTone K192940	Subject Device CoolTone	Comments
Automatic Shut Off?	Yes	Same	Unit shuts off with specified timer
Patient Override Control?	No	Same	Treatment is delivered by healthcare provider
Indicator Display: - On/Off Status? - Low Battery? - Voltage/Current Level?	 Yes N/A No	Same	
Timer Range (minutes)	Up to 30 min	Same	
Compliance with Voluntary Standards?	Yes	Same	Refer to performance data for details
Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes	Same	
Weight	80 Kg	Same	
Housing Materials and Construction	Steel and Injection Molded Plastics	Same	
Waveform (e.g., pulsed monophasic, biphasic)	Symmetrical Biphasic Sine Wave	Same	
Shape (e.g., rectangular, spike, rectified sinusoidal)	Sinusoidal	Same	
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
Frequency (Hz)	1-150 Hz	Same	
For interferential modes only: - Beat Frequency (Hz)	N/A	N/A	
For multiphasic waveforms only: - Symmetrical phases?	Yes	Same	Biphasic
Phase Duration (include units) (state range, if applicable)	370 µs +/- 20%	Same	

Technological Characteristics	Predicate Device CoolTone K192940	Subject Device CoolTone	Comments
(both phases, if asymmetrical)			
Net Charge (mC per pulse) (If zero, state method of achieving zero net charge.)	N/A	N/A	No electrodes - applicators are not connected to patient
Maximum Phase Charge, (mC)	N/A	N/A	No electrodes - applicators are not connected to patient
Maximum Current Density, (mA/cm^2)	N/A	N/A	No electrodes - applicators are not connected to patient
Maximum Power Density, (W/cm^2) (using smallest electrode conductive surface area)	N/A	N/A	No electrodes - applicators are not connected to 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	

VII. PERFORMANCE DATA:

The CoolTone System is the same as the previously cleared predicate device (K192940). It has been tested/assessed against and fully complies with the following voluntary standards:

Table 6.3: Compliance with Voluntary Standards

Standards	Standards Organization	Standards Title
ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012	ANSI AAMI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Standards	Standards Organization	Standards Title
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
60601-1-6:2013 (Edition 3.1)	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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
62366-1:2015 (Edition 1.0)	IEC	Medical devices – Application of usability engineering to medical devices
62304:2015 (Edition 1.1)	ISO	Medical devices software –software life cycle processes
14971:2012	ISO	Medical devices – Application of risk management to medical devices
10993-1: 2018	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Software verification was performed in three steps: verification of the software requirements, verification of the design specifications and verification of the software architecture. All tests, including Integration Tests (Tests of the System Architecture and the

Design Specification) and the System Level Test (Test of functional requirements that were evaluated in the software requirements verification) were performed successfully and met their acceptance criteria.

Cybersecurity
Cybersecurity risk management for the device was performed as part of the overall risk management process for the medical device and follows the guidance in the FDA document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The changes made to the predicate's (K192940) system software have no impact on cybersecurity.

Biocompatibility Testing
There were no changes to patient-contacting materials in comparison with the previously cleared predicate device.

Electrical safety and electromagnetic compatibility (EMC)
The CoolTone system (control unit and applicator) has undergone electrical and mechanical safety performance testing as a result of the changes referenced. Additionally, the control unit underwent electromagnetic compatibility testing. The applicator did not require additional electromagnetic compatibility testing because the changes did not affect its electromagnetic compatibility.
The system complies with ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012), and IEC 60601-1-2:2014 (Fourth Edition).

Performance Testing
The proposed CoolTone system performance is the same as the previously cleared predicate device.
The System Level 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 is not subjected to an appreciable rise in temperature at maximum intensity to cause a risk to the patient.

Clinical Study
No clinical testing was required for these changes.

VIII. CONCLUSION:

The Indication for Use for the subject CoolTone system is the same as the predicate device cleared in K192940. The changes that have been made to the system's hardware and software do not affect the intended use, performance or risk profile of the device. The subject CoolTone system is therefore substantially equivalent to the predicate device.