July 14, 2025

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Consultant
QARA Consulting
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K251378
Trade/Device Name: CoolTone
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 16, 2025
Received: June 16, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tushar Bansal -S

Tushar Bansal, PhD
Assistant Director, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251378

Device Name

CoolTone

Indications for Use *(Describe)*

- 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.

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

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K251378
510(K) SUMMARY

SUBMITTER:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm, Germany Establishment Registration: 8010720
CONTACT:	Mrs. Ute Killet Manager, Regulatory Affairs Phone: +49-731-9761-216 Fax: +49-731-9761-118 E-mail: u.killet@zimmer.de

DATE PREPARED:	May 30, 2025
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
PREDICATE DEVICE:	CoolTone (K220601)

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.

INDICATIONS 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:
The technological characteristics of the subject device and the predicate device are identical.

Table 1: Technological Similarities between Proposed and Predicate Device

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone (K251378)	PREDICATE DEVICE Zimmer MedizinSyteme GmbH CoolTone (K220601)
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
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 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.
Primary Function	Muscle stimulation	Muscle stimulation

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone (K251378)	PREDICATE DEVICE Zimmer MedizinSyteme GmbH CoolTone (K220601)
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”	12”
Positioning of Applicator	Securement system	Securement system
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 – 1.35T +/- 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	Up to two large applicators can be operational at same time
Applicator connection	Detachable from the control unit	Detachable from the control unit
Total Induced Current in Tissue (mA)	327	327
Type of Operation	Continuous	Continuous
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz
Pulse Duration	Large applicator 370 µs +/- 20%	Large applicator 370 µs +/- 20%
Pulse Amplitude	0 – 100 %	0 – 100 %
Selection of parameters (Intensity, Time)	Yes	Yes
Treatment Time	Up to 30 min	Up to 30 min
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave
Energy Source	100 - 240 VAC, 50-60 Hz	100 – 240 VAC, 50–60 Hz
System Dimensions (WxHxD)	600 x 1100x 600 mm	600 x 1100x 600 mm
Operating Ambient Temperature	10°C to 28 °C	10°C to 28 °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 (K251378)	PREDICATE DEVICE Zimmer MedizinSyteme GmbH CoolTone (K220601)	Comments
4. Power Source(s) - Method of Line Current Isolation - Patient Leakage Current Normal condition Single fault condition	60601 compliant < 100 µA 3.9 µA	60601 compliant < 100 µA 3.9 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 Synchronous N/A	No electrodes - applicators are not connected to patient
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

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone (K251378)	PREDICATE DEVICE Zimmer MedizinSyteme GmbH CoolTone (K220601)	Comments
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 30 Min	
15. Compliance with Voluntary Standards?	Yes	Yes	
16. Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes	Yes	
17. Weight	80 Kg	80 Kg	
19. Housing Materials and Construction	Steel and Injection Molded Plastics	Steel and Injection Molded Plastics	
Waveform (e.g., pulsed monophasic, biphasic)	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	
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	

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone (K251378)	PREDICATE DEVICE Zimmer MedizinSyteme GmbH CoolTone (K220601)	Comments
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%	370 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 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	

Sections 2,3 Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH CoolTone (K251378)	PREDICATE DEVICE Zimmer MedizinSyteme GmbH CoolTone (K220601)	Comments
OFF Time (seconds)	N/A	N/A	
Additional Features (if applicable)	N/A	N/A	

Product Labeling

This premarket submission included changes in product labeling. The user's manual was updated to capture information obtained in post-market surveillance activity. The labeling changes described in the submission do not affect the intended use, performance or risk profile of the device.

Clinical Study

No clinical testing was required for this change.

Substantial Equivalence Determination

a. Intended Use: There is no change to the indications for use for this submission between the subject and predicate device (K220601).
b. Technological Characteristics: The CoolTone has the same technological characteristics as the predicate device (K220601).
c. Labeling: The changes in labeling described in this submission does not create any new questions of safety and performance as compared to the predicate device.

The CoolTone is substantially equivalent to the predicate K220601.