January 16, 2026

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

Re: K253408
Trade/Device Name: CoolTone
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, IPF
Dated: December 16, 2025
Received: December 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
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253408

Please provide the device trade name(s).

CoolTone

Please provide your Indications for Use below.

CoolTone device is indicate 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

When intended to stimulate healthy muscles to improve or facilitate muscle performance, CoolTone induces muscle contractions to enhance muscle function and may therefore be considered a technique of muscle training.

In addition, the CoolTone is indicated to be used for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle reeducation
- Maintaining or increasing the range of motion

CoolTone may also be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. Furthermore, CoolTone device may be used to stimulate neuromuscular tissue for bulk muscle excitation in the legs for rehabilitative purposes.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
Cooltone
K253408

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

SUBMITTER:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm, Germany Establishment Registration: 8010720
OFFICIAL CORRESPONDENT:	Scott Blood, RAC-Devices Principal Consultant Phone: 978.729.5978 Fax: +49 731 9761 118 E-Mail: scottqara@gmail.com
DATE PREPARED:	November 11, 2025
TRADE NAME:	CoolTone
COMMON NAME:	Powered Muscle Stimulator
REGULATION NUMBER	21 CFR 890.5850
REGULATION NAME:	Powered Muscle Stimulator
REGULATORY CLASS:	Class II
PRODUCT CODE:	NGX, IPF
PREDICATE DEVICE:	BTL-899MS (K240234)
REFERENCE DEVICE:	CoolTone (K251378)

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, CoolTone helps to strengthen, tone and firm the abdomen, buttocks and thighs.

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

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. CoolTone is equipped with a 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.

Table 1: Indications for Use Comparison between Subject and Predicate Device

Indications for Use	**Subject Device** **Zimmer MedizinSysteme GmbH** **CoolTone System** **K253408**	**Predicate Device** **BTL Industries, Inc** **BTL-899MS** **K240234**
Indications For Use	CoolTone device 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 When intended to stimulate healthy muscles to improve or facilitate muscle performance. CoolTone induces muscle contractions to enhance muscle function and may	BTL-899MS 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, thighs and calves. • Improvement of muscle tone and firmness, for strengthening muscles in arms. The BTL-899MS device is intended to be used under medical supervision for adjunctive therapy for the

Indications for Use	Subject Device Zimmer MedizinSysteme GmbH CoolTone System K253408	Predicate Device BTL Industries, Inc BTL-899MS K240234
	therefore be considered a technique of muscle training. In addition, the CoolTone is indicated to be used for: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle reeducation • Maintaining or increasing the range of motion CoolTone may also be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. Furthermore, CoolTone device may be used to stimulate neuromuscular tissue for bulk muscle excitation in the legs for rehabilitative purposes.	treatment of medical diseases and conditions. The BTL-899MS device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: • 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 • Maintaining or increasing the range of motion

COMPARISON OF INDICATIONS FOR USE WITH THE PREDICATE DEVICE

The subject CoolTone device has the same indications for use as the predicate device and is commonly cleared by the FDA for 21 CFR 890.5850 powered muscle stimulators.

The subject device intends to add the standard indications for use for Powered Muscle Stimulators classified under product code IPF and 21 CFR 890.5850 (FDA Guidance Document for Powered Muscle Stimulator 510(k)s) for use in physical medicine and rehabilitation.

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle reeducation
- Maintaining or increasing the range of motion

The subject device is also intended to stimulate healthy muscles to improve or facilitate muscle performance.

Table 2: Technological Characteristics Comparison between Subject and Predicate Device

Attribute	Subject Device Zimmer MedizinSysteme GmbH CoolTone System K253408	Predicate Device BTL Industries, Inc BTL-899MS K240234	Substantial Equivalence Assessment
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 NGX-Stimulator, Muscle, Powered, Muscle Conditioning IPF – Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered NGX – Stimulator, Muscle, Powered, Muscle Conditioning	Identical
Primary Function	Muscle Stimulation	Muscle Stimulation	Identical
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Identical
Clinical Use	Prescription Use	Prescription use	Identical
Electrical Protection	Class I, BF	Class II, BF	Different
User Interface	Touch screen, 12''	Touch screen	Identical
Firmware Controlled	Yes	Yes	Identical
Type of Energy	Magnetic field	Magnetic Field	Identical
Stimulation Method	Electromagnetic Stimulation	Electromagnetic stimulation	Different

Attribute	Subject Device Zimmer MedizinSysteme GmbH CoolTone System K253408	Predicate Device BTL Industries, Inc BTL-899MS K240234	Substantial Equivalence Assessment
		accompanied by bipolar radiofrequency	
Delivery Method	Applicator with internal coils (non-contact)	Applicator with internal coils (non-contact)	Identical
Positioning	Securement system for Applicators	Securement system for Applicators	Identical
Number of outputs	2	2	Identical
Number of Applicators	Up to two applicators can be operational at same time	2	Identical
Total Induced Current in Tissue (mA)	327	Not publicly available	Could not be compared
Type of Operation	Continuous	Continuous	Identical
Number of Magnetic coils in the Applicators	1	1	Identical
Magnetic Field Intensity	0.5-1.35T ± 20%	AP-C-1 - 0.5 to 1.8 T +/- 20% AP-C-2 - 0.7 to 2.0 T +/- 20%	Different
Magnetic Energy Density (Range)	36.80 – 268.31 J/m^3	AP-C-1: 21.93 - 284.26 J/m^3 AP-c-2: 19.8 - 161.59 J/m^3	Different

Attribute	Subject Device Zimmer MedizinSysteme GmbH CoolTone System K253408	Predicate Device BTL Industries, Inc BTL-899MS K240234	Substantial Equivalence Assessment
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	Identical
Pulse Duration	370 µs ± 20%	AP-C-1 - 280 µs ± 20% AP-C-2 - 190 µs ± 20%	Different
Pulse Amplitude	0 – 100%	0–100 %	Identical
Selection of parameters (Intensity, Time)	Yes	Yes	Identical
Therapy Time	Up to 30 min	Up to 30 min	Identical
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	Identical
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	Identical
System Dimensions (WxHxD)	600x1100x600 mm	23 x 39 x 29 in (592 x 985 x 730 mm)	Similar
System Weight	80kg	70 kg	Similar
Ambient Storage Temperature	-10° C to +60° C	-10° C to +55° C	Similar
Relative Storage Humidity	10% to 90%	10% to 85%	Similar
Environmental Specifications	For indoor use only	For indoor use only	Identical

DISCUSSION OF TECHNOLOGICAL CHARACTERISTIC DIFFERENCES BETWEEN THE SUBJECT DEVICE AND THE PREDICATE DEVICE

The subject CoolTone device is identical in technological characteristics to the previous CoolTone device that was cleared in K251378, mentioned as reference device in this submission.

Technological Characteristics	Characteristic difference between CoolTone and BTL-899MS	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Electrical Protection	CoolTone: Class I, BF BTL-899MS: Class II, BF	Per IEC 60601-1: Class I equipment is designed to protect against electric shock by providing an additional safety ground, which is connected to the internal and/or external conductive parts of the power source. This means that if the basic insulation fails, the equipment can still be safe to use. Class II equipment, on the other hand, relies on additional insulation layers to provide protection against electric shock, such as double insulation or reinforced insulation. These devices do not require a protective earth ground and are designed to operate safely without relying on basic insulation alone. The differences in electrical protection have been built into the respective device designs and verified by certified lab testing.
Magnetic Field Intensity	CoolTone: 0.5-1.35T ± 20% BTL-899MS: AP-C-1 - 0.5 to 1.8 T +/-20% AP-C-2 - 0.7 to 2.0 T +/-20%	Effectiveness of magnetic field therapy is quantified by field intensity and pulse width. Therefore, the lower maximum of magnetic field intensity of the subject device (1.35 T +20%) compared to the predicate device (2.0T) is compensated by the longer pulse width (370µs) of the subject device compared to the predicate device (190-280µs). Taking this into consideration the subject device is as effective as the predicate device. The magnetic field intensity of the subject CoolTone device is within the typical clinical range observed in other comparable Class II powered muscle stimulator devices cleared under 21 CFR 890.5850 with product codes NGX (e.g., CoolTone, K251378) and IPF (e.g., emFieldPro, K182963), which have similar intended uses and technology. Since FDA has previously cleared devices under the same regulation and product codes with comparable intended use, technology, and magnetic field intensity without identifying safety or effectiveness concerns, this difference does not impact safety and effectiveness of the subject device.

Technological Characteristics	Characteristic difference between CoolTone and BTL-899MS	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Magnetic Energy Density (Range)	CoolTone: 36.80 – 268.31 J/m^3 BTL-899MS: AP-C-1: 21.93 - 284.26 J/m^3 AP-c-2: 19.8 - 161.59 J/m^3	The magnetic energy density range of the subject device is within the range of values of the predicate (K240234) device, which is cleared for the same indications as the subject. Therefore, these differences do not raise any unacceptable risks or any unacceptable safety or effectiveness questions compared to the predicate devices.
Pulse Duration:	CoolTone: 370 µs ± 20% BTL-899MS: AP-C-1 - 280 µs ± 20% AP-C-2 - 190 µs ± 20%	The pulse duration of the subject CoolTone device differs from that of the predicate device but remains within the typical clinical range observed in other comparable Class II powered muscle stimulator devices cleared under 21 CFR 890.5850 with product codes NGX (e.g., CoolTone, K251378) and IPF (e.g., emFieldPro, K182963), which have similar intended uses and technology. Since FDA has previously cleared devices under the same regulation and product codes with comparable intended use, technology, and pulse duration without identifying safety or effectiveness concerns, this difference does not impact safety and effectiveness of the subject device.
System Dimensions and Weight	CoolTone: 600x1100x600 mm and 80kg BTL-889MS: 592 x 985 x 730 mm and 70kg	Different device form factors have no influence on the safety or effectiveness of the device.
Storage Temperature and Relative Humidity	CoolTone: -10° C to +60° C and 10% to 90% BTL-889MS: -10° C to +55° C and 10% to 85%	Both the subject device and the predicate device are well within the use ranges that are expected of office-based medical devices. The differences here are not important for the device safety and effectiveness evaluation.

The differences in the subject device's technological characteristics compared to the predicate devices do not raise different questions of safety or effectiveness.

In comparison with the previously cleared CoolTone device (K251378), the following changes have been made to the subject device:

Labeling:

- The user's manual was updated to capture the updated indications for use.

Summary of Non-clinical Testing:

The technological characteristics of the CoolTone device have been verified based on assessments of electrical safety, electromagnetic compatibility, and software.

The device has been found to comply with applicable medical device safety standards:

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbance – Requirements and tests

IEC TS 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

IEC 62304 Medical device software – Software life cycle processes

ISO 14971 Medical devices – Application of risk management to medical devices

The following testing has been conducted with satisfactory results:

Electromagnetic compatibility: EMC testing was done to evaluate emissions and immunity to electromagnetic fields in accordance with IEC 60601-1-2 and IEC 60601-4-2.

Electrical safety: Full electrical safety testing was done in compliance with IEC 60601-1.

Testing has been performed on final, finished devices and these systems have met the required specifications for the completed tests.

Clinical Testing:

No clinical testing was required for this change.

CONCLUSIONS

The subject CoolTone device has the same intended use as its predicate device. While there are minor differences in technological characteristics of the subject device and the predicate device, these differences do not raise different questions of safety and effectiveness and the performance data provided in this submission demonstrates substantial equivalence. Therefore, the subject CoolTone device is substantially equivalent to the predicate device.