May 19, 2025

Zhengzhou PZ Laser Slim Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K250038
Trade/Device Name: Muscle Stimulator Device (PZ-100)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 21, 2025
Received: April 21, 2025

Dear Ray Wang:

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

for Heather Dean, Ph.D
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)*

K250038

Device Name

Muscle Stimulator Device (PZ-100)

Indications for Use *(Describe)*

The Muscle Stimulator Device 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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The assigned 510(k) Number: K250038

510(k) Summary

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

1. Date of Preparation: 05/13/2025

2. Sponsor Identification

Zhengzhou PZ Laser Slim Technology Co., Ltd.
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3. Designated Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
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Contact Person: Ray Wang
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Email: information@believe-med.com

4. Identification of Proposed Device

Trade Name: Muscle Stimulator Device
Model: PZ-100
Common Name: Stimulator, Muscle, Powered, For Muscle Conditioning

Regulatory Information
Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning
Classification: II
Product Code: NGX

Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Review Panel: Physical Medicine

Indication for use Statement:

The Muscle Stimulator Device 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.

Device Description:

The Muscle Stimulator Device (model PZ-100) is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. The device has four outputs, and two applicators perform simultaneous treatment.

The Muscle Stimulator Device is equipped with a large color touch screen with wide view angle that significantly facilitates the use of the device. The on-screen information guides the user stepby-step through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen of the device. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

The Muscle Stimulator Device is composed of control display panel module, main control module, temperature module, treatement handle module, and fan cooling module.

The Muscle Stimulator Device 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 proposed device can simultaneously apply multiple treatment handles to patients, and the handles are held in place by bandages.

5. Identification of Predicate Device(s)

Predicate Device:
510(k) Number: K190456
Product Name: BTL 799-2L
Manufacturer: BTL Industries, Inc.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-10:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-6:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Proposed Device (K250038)**	**Predicate Device (K190456)** **BTL 799-2L**	**Remark**
Product Code	NGX	NGX	SAME
Regulation No.	21 CFR 890.5850	21 CFR 890.5850	SAME
Classification	II	II	SAME
Regulation Name	Stimulator, Muscle, Powered, For Muscle Conditioning	Stimulator, Muscle, Powered, For Muscle Conditioningr	SAME
Indications for use	The Muscle Stimulator Device 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.	BTL 799-2L 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.	SAME

Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	SAME
Clinical Use	Prescription use	Prescription use	SAME
Electrical Protection	Class I, BF	Class II, BF	Difference 1
User Interface	Touch screen	Touch screen	SAME
Firmware Controlled	Yes	Yes	SAME
Type of Energy	Magnetic field	Magnetic field	SAME
Number of outputs	4	2	Difference 2
Number of Magnetic Coils in the Applicator	1	1	SAME
Magnetic Field Intensity	PZ 100-A & PZ 100-B: 0.5 - 1.8 T ±20%	BTL 299-6 applicator: 0.5 - 1.8 T ±20%	SAME
	PZ 100-C & PZ 100-D: 0.7 - 2.0 T ±20%	BTL 299-7 applicator: 0.7 - 2.0 T ±20%	SAME
Maximum Magnetic Field Intensity at Applicator Center Surface	PZ 100-A & PZ 100-B: 1.154 T ±20%	BTL 299-6 applicator: 1.154 T ±20%	SAME
	PZ 100-C & PZ 100-D: 1.130 T ±20%	BTL 299-7 applicator: 1.173 T ±20%	Difference 3
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	SAME
Pulse Duration	280 ± 10% µs	BTL 299-6 applicator: 280 ± 20% µs	SAME
		BTL 299-7 applicator: 190 ± 20% µs	Difference 4
Selection of parameters (Intensity, Time)	Yes	Yes	SAME
Therapy Time	5-60 min	Up to 60 min	Difference 5
Energy Source	100 – 120 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	Difference 6
System Dimensions (W×H×D)	567×1148×380 mm (22×45×15 in)	580×1380×580 mm (23×55×23 in)	Difference 7
Applicator dimensions	PZ 100-A & PZ 100-B: 287*170*86mm PZ 100-C & PZ 100-D: 292*170*77mm	BTL 299-6 applicator: 267*182*83mm BTL 299-7 applicator: 267*182*83mm	Difference 8
Applicator surface area	PZ 100-A & PZ 100-B: 200.96cm^2 PZ 100-C & PZ 100-D: 184.08cm^2	BTL 299-6 applicator: 206.02cm^2 BTL 299-7 applicator: 206.02cm^2	Difference 9
Ambient Temperature	5℃ ~ 30℃	-10°C to +55°C	Difference 10
Relative Humidity	≤80%	10% to 85%	Difference 11
Environmental Specifications	For indoor use only	For indoor use only	SAME
Applied Standards:			
Biocompatibility	ISO 10993-5, ISO 10993-10, ISO 10993-23	ISO 10993-1, ISO 10993-5, ISO 10993-10	Different 12

Electrical Safety	IEC 60601-1 and IEC 60601-1-6	IEC 60601-1 and IEC 60601-1-6	SAME
EMC	IEC 60601-1-2	IEC 60601-1-2	SAME
Performance	IEC 60601-2-10	IEC 60601-2-10	SAME

Analysis 1/6:

The proposed device is different in Electrical Protection and Energy Source from the predicate device (K190456). The CLASSIFICATION OF ME EQUIPMENT of the predicate device is Class II, and the proposed device is Class I. Both of them meet the requirements of IEC 60601-1, so we believe that this difference will not raise any risks in safety and effectiveness, both the proposed device and predicate device (K190456) are safe and effective.

Analysis 2:

The proposed device is different in Number of outputs from the predicate device (K190456). The Number of outputs of the predicate device is 2, and the proposed device is 4. Both of them meet the requirements of IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10, so we believe that this difference will not raise any risks in safety and effectiveness, both the proposed device and predicate device (K190456) are safe and effective.

Analysis 3:

The proposed device is different in Maximum Magnetic Field Intensity at Applicator Center Surface from the BTL 299-7 applicator of predicate device (K190456). The Maximum Magnetic Field Intensity at Applicator Center Surface of the predicate device is 1.173 T±20%, and the 100-C & PZ 100-D (proposed device) are 1.130 T ±20%. The proposed device is within the allowable error range of the predicate device, so we believe that this difference will not raise any risks in safety and effectiveness, both the proposed device and predicate device (K190456) are safe and effective.

Analysis 4:

The proposed device is different in Pulse Duration from the predicate device (K190456). The Pulse Duration of the BTL 299-7 applicator (predicate device) is 190 ± 20% μs, and the 100-C & PZ 100-D (proposed device) are 280 ± 10% μs. Pulse width of 280 ± 10% μs for the proposed stimulation areas for this indication has been previously cleared. Therefore, the difference in pulse width does not raise new question of safety and effectiveness.

Analysis 5:

The proposed device is different in Therapy Time from the predicate device (K190456). The Therapy Time of the predicate device is up to 60 min, and the proposed device is 5-60min. We believe that this minor difference will not raise any risks in safety and effectiveness, both the proposed device and predicate device (K190456) are safe and effective.

Analysis 7/10/11:

The proposed device is different in System Dimensions, Ambient Temperature and Relative Humidity from the predicate device (K190456). However, the configuration difference are just in physical specification and this difference will not raise any issues in safety and effectiveness. By

complying with IEC 60601-1, the mechanical performance, Ambient Temperature and Relative Humidity of the proposed device is determined to be accepted. Therefore, these difference will not affect safety and effectiveness of the proposed device.

Analysis 8/9:

The proposed device is different in Applicator dimensions and Applicator surface area from the predicate device (K190456). The proposed device's Applicator dimensions and Applicator surface area have slight differences from the predicate device, but both are within the allowable error range, which is ±20%. We believe that this minor difference will not raise any risks in safety and effectiveness, both the proposed device and predicate device (K190456) are safe and effective.

Analysis 12:

The proposed device is different in Biocompatibility Testing Standard from the predicate device (K190456). The proposed device was tested according to ISO 10993-1. We tested ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021, which are FDA recognized standard. Therefore, this difference will not affect the safety in Biocompatibility of the proposed device.

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and is substantially equivalent to the legally marketed predicate device (K190456).