August 13, 2026

Beijing Winkonlaser Technology Limited
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Bldg. #15, Xiyuehui, #5, Yihe N. Rd.
Fangshan District
Beijing, 102401
China

Re: K253790
Trade/Device Name: High Intensity Focused Electromagnetic Stimulation Device (FE60)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 17, 2026
Received: July 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K253790

Please provide the device trade name(s).

High Intensity Focused Electromagnetic Stimulation Device (FE60)

Please provide your Indications for Use below.

The FE60 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.

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

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

The assigned 510(k) Number: K253790

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: 08/12/2026

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: High Intensity Focused Electromagnetic Stimulation Device
Model: FE60
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 FE60 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 High Intensity Focused Electromagnetic Stimulation Device (Model: FE60) is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body.

The proposed device can simultaneously apply multiple treatment applicators to patients, and the applicators are held in place by straps. The device has four outputs, two flat, two curved—to fit various body parts. The B1 and B2 applicators are flat applicators suitable for the abdomen and buttocks; The A1 and A2 applicators are curved applicators, suitable for the arms, thighs, and calves;

The High Intensity Focused Electromagnetic Stimulation Device (Model: FE60) 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. Easily adjust programs, parameters, and treatment durations using the intuitive touchscreen interface. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

The High Intensity Focused Electromagnetic Stimulation Device (Model: FE60) is composed of control display panel module, main control module, temperature module, treatement handle module, and fan cooling module.

5. Identification of Predicate Device(s)

Predicate Device:
510(k) Number: K250038
Product Name: Muscle Stimulator Device (Model: PZ-100)
Manufacturer: Zhengzhou PZ Laser Slim Technology Co., Ltd.

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

Additionally, biocompatibility assessment was conducted per *Attachment G: Biocompatibility of Certain Devices in Contact with Intact Skin* of the FDA biocompatibility guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Proposed Device**	**Predicate Device (K250038)** **Muscle Stimulator Device**	**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 Conditioning	SAME
Indications for use	The FE60 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 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.	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 I, BF	SAME
User Interface	Touch screen	Touch screen	SAME
Firmware Controlled	Yes	Yes	SAME
Type of Energy	Magnetic field	Magnetic field	SAME
Number of outputs	4	4	SAME
Number of Magnetic Coils in the Applicator	1	1	SAME
Magnetic Field Intensity	0.55-1.89 T ±20% (per Flat Applicator)	PZ 100-A & PZ 100-B: 0.5 - 1.8 T ±20%	Difference 1
	0.95–2.04 T ±20% (per Curved applicator)	PZ 100-C & PZ 100-D: 0.7 - 2.0 T ±20%	Difference 1
Maximum Magnetic Field Intensity at Applicator Center Surface	1.28 T ±20% (per Flat Applicator)	PZ 100-A & PZ 100-B: 1.154 T ±20%	Difference 2
	0.96 T ±20% (per Curved applicator)	PZ 100-C & PZ 100-D: 1.130 T ±20%	Difference 2
Pulse Repetition Rate	1-150 Hz	1 – 150 Hz	SAME
Pulse Duration	280 ± 20% µs	280 ± 10% µs	SAME
Selection of parameters (Intensity, Time)	Yes	Yes	SAME
Therapy Time	Up to 60 min	5-60 min	Difference 3
Energy Source	AC 110V, 50/60 Hz	100 – 120 V AC, 50–60 Hz	Difference 4
System Dimensions	137*53*49 cm	567×1148×380 mm (22×45×15 in)	Difference 4
Applicator dimensions	305*176*100 mm (per Flat Applicator) 283*177.26*87.85 mm (per Curved Applicator)	PZ 100-A & PZ 100-B: 287*170*86mm PZ 100-C & PZ 100-D: 292*170*77mm	Difference 4
Applicator surface area	B1 & B2: 247.45cm^2 (Flat Applicator) A1 & A2: 221.25cm^2 (Curved Applicator)	PZ 100-A & PZ 100-B: 200.96cm^2 PZ 100-C & PZ 100-D: 184.08cm^2	Difference 5
Ambient Temperature	10°C to 30°C	5°C ~ 30°C	Difference 4
Relative Humidity	≤80%	≤80%	SAME
Environmental Specifications	For indoor use only	For indoor use only	SAME
Applied Standards:			
Biocompatibility	ISO 10993-1	ISO 10993-5, ISO 10993-10, ISO 10993-23	Difference 6
Electrical Safety	IEC 60601-1	IEC 60601-1	SAME
EMC	IEC 60601-1-2	IEC 60601-1-2	SAME
Performance	IEC 60601-2-10	IEC 60601-2-10	SAME

Analysis 1:

The proposed device is different in Magnetic Field Intensity from the predicate device (K250038). The Magnetic Field Intensity of the PZ 100-A & PZ 100-B are: 0.5-1.8 T ±20%, PZ 100-C & PZ 100-D are 0.7-2.0T ±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.

Analysis 2:

The proposed device is different in Maximum Magnetic Field Intensity at Applicator Center Surface from the predicate device (K250038). The Maximum Magnetic Field Intensity at Applicator Center Surface of the PZ 100-A & PZ 100-B are 1.154 T±20%, PZ 100-C & PZ 100-D 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.

Analysis 3:

The proposed device is different in Therapy Time from the predicate device (K250038). The Therapy Time of the predicate device is 5-60min, and the proposed device is up to 60 min. We believe that this minor difference will not raise any risks in safety and effectiveness

Analysis 4:

The proposed device is different in Energy Source, System Dimensions, Applicator dimensions and Ambient Temperature from the predicate device (K250038). 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 5:

The proposed device's Applicator surface area have slight differences from the predicate device (K250038), but the applicator (flat handle and curved handle) surface area of the predicate device are within the allowable error range of proposed device, 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 (K250038) are safe and effective.

Analysis 6:

To support biocompatibility of the tissue contacting Applicator and Straps, information was provided per *Attachment G: Biocompatibility of Certain Devices in Contact with Intact Skin* of the FDA biocompatibility guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" consistent with ISO 10993-1 principles for the evaluation of biological safety within a risk management process.

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and is substantially equivalent to the legally marketed predicate device (K250038).