April 10, 2026

ShenB Co., Ltd.
% Connie Hoy
Consultant
Hoy & Associates Regulatory Consulting, LLC
1830 Bonnie Way
Sacramento, California 95825

Re: K253926
Trade/Device Name: Diacore
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 8, 2025
Received: December 8, 2025

Dear Connie Hoy:

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

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)*
K253926

Device Name
Diacore

Indications for Use *(Describe)*
DIACORE 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.

510(K) Summary
Diacore

Applicant	ShenB Co., Ltd.
Address	SHENB Tower, 74, Achasan-ro, Seongdong-gu, Seoul Republic of Korea
Telephone	82-466-0010
Contact Person	Connie Hoy, Regulatory Consultant
Contact Information	conniehoy@hoyregulatory.com
Preparation Date	April 5, 2026
510K number	K253926
Device Trade Name	Diacore
Classification Name	Powered Muscle Stimulator
Regulation Number	21 CFR 890.5850
Product Code	NGX
Regulatory Class	II
Predicate Device	Body Contouring Machine manufactured by Hebei JT Medical Co., Ltd. K232181

1.0 Device Description:

The Diacore High-Frequency Electromagnetic Stimulator is a non-invasive electromagnetic muscle stimulator that applies high-intensity electromagnetic field to the treatable body areas through three different applicator types. The coil enclosed in each applicator produces a magnetic field that induces electric currents within neuromuscular tissues. At its optimal level, these electric currents depolarize neuromuscular tissues causing effective muscle contraction.

Diacore consists of a Main Body, a software integrated color-touch LCD screen and three applicators (Standard, Large and Circle). The Main Body allows the proper operation of the entire system. The LCD screen works as a control panel and displays step-by-step guides through the entire therapy procedure. The therapeutic parameters such as treatment time, location, and stimulation frequency and intensity are easily set using the touch screen and the dial knob on the device. The micro-controller within the software continuously monitors the device system for its operation and functional normalcies.

510(K) Summary
Diacore

The device is a mobile standalone equipment with four wheels. The device housing protects the patient from electrical shock and mechanical injuries. The device is operated through a graphic user interface on an LCD screen and is intended to be operated by medical professionals.

2.0 Indications for use:

DIACORE 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.

3.0 Comparison

Category	Device	Primary Predicate Device	Equivalence
Manufacturer	ShenB Co., Ltd	Hebei JT Medical Co., Ltd.	N/A
Product Name	DiaCore	Body Contouring Machine	N/A
Model Name	DiaCore	Model(s): CS2,CS3,CS5,CS7,CS8,CS11,CS13	N/A
License / Registration Number	K253926	K232181	N/A
Regulatory Name / Code / Class	890.5850 Powered muscle stimulator. Stimulator, Muscle, Powered, Muscle Conditioning [NGX] Class 2	890.5850 Powered muscle stimulator. Stimulator, Muscle, Powered, Muscle Conditioning [NGX] Class 2	Same
Indications for Use	• Improvement of abdominal tone, strengthening of the abdominal muscles,	• Improvement of abdominal tone, strengthening of the abdominal muscles,	Same

Category	Device	Primary Predicate Device	Equivalence
	development of firmer abdomen. • Strengthening, Toning and Firming of buttocks, thighs and calves. • Improvement of muscle tone and firmness, for strengthening muscles in arms.	development of firmer abdomen. • Strengthening, Toning and Firming of buttocks, thighs and calves. • Improvement of muscle tone and firmness, for strengthening muscles in arms.	
Principle of Action	Initiating action potential of nerves resulting in muscle contraction	Initiating action potential of nerves resulting in muscle contraction	Same
User Interface	Touch Screen	Touch Screen	Same
Type of Energy	Magnetic Field	Magnetic Field	Same
Pulse Width	Large applicator: 340μs ± 20% Standard applicator: 285μs ± 20% Circle applicator: 175μs ± 20%	300±20μs 190±20μs	Different *1
Electromagnetic Field Intensity (output value)	Large applicator: 1.3 - 2.5T +/-20% Standard applicator: 1.3 - 2.5T +/-20% Circle applicator: 0.5 - 2.5T +/-20%	ZH-01 applicator: 0.1-1.8T±20% ZH-03 applicator: 0.1-2.5T±20%	Same
Pulse Repetition Rate	1 ~ 150Hz	1 ~ 150Hz	Same
Therapy Time	0 ~ 60 min	0 ~ 60 min	Same
Energy Source	110~230 VAC, 50-60Hz	220/110V ,50–60 Hz	Same

4.0 Performance Testing

Verification and validation activities were successfully completed and established that the Diacore performs as intended. Testing included the following:

- IEC 60601-1:2005 + A2:2020; Medical Electrical Equipment- Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 + A1:2020; 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 Edition 2.1 2016-04; Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
- EN ISO 14971:2019; Medical Devices – Application Of Risk Management To Medical Devices
- IEC TR 60601-4-2 Edition 1.0 2016-05: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and
- testing within a risk management process
- ISO 10993-10:2010, Biological Evaluation of Medical Device , Part 10-Test for Irritation and skin sensitization
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Bench Testing - Bench testing was performed to measure magnetic fields produced by the Shen B Diacore device throughout the spatial regions comprising the intended treatment areas for each of the device's applicators.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Biocompatibility – Patient contacting materials have been determined to be biocompatible.

5.0 Discussion

The Diacore is nearly identical to the predicate device with the exception of the pulse duration. Both devices (subject and predicate) share the same output range and tolerance from 0.1 to 2.5T +/-20% thus avoiding any new safety implications.

Regarding pulse width, the predicate device (K232181) pulse width across applicator types ranges from 190µs - 300µs +/-20%. Similarly the Subject device (ShenB DIACORE) pulse width across applicator types ranges from 175µs - 340µs +/-20%. Thus both the subject and predicate devices largely occupy the same range of pulse durations with only small excursions at either end of the range.

Both the circle and standard applicators for the subject device have maximum pulse durations less than the predicate device and the subject device large applicator has a pulse duration only slightly above the predicate at 340µs +/-20% vs. 300µs +/-20%, a narrow difference of only 40µs. Given the equivalent maximum magnetic field intensity and the largely equivalent pulse duration range of the subject device compared to the predicate device, the subject device is shown to be substantially equivalent.

6.0 Conclusion

The Diacore (subject device) has the same intended use, indication for use and technology as the predicate device. The minor difference does raise any new concerns for safety and efficacy. Therefore, the Diacore device has been shown to be substantially equivalent to currently marketed predicate device.