



April 10, 2024

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
Building 11, Lane 1566, Nanle Road, Songjiang District
Shanghai, Shanghai 201613
China

Re: K232409

Trade/Device Name: Electromagnetic Stimulation Systems
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 10, 2024
Received: March 11, 2024

Dear Felix Li:

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.

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,

Julia E. 2024.04.10
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for Heather Dean, PhD

Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation 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

510(k) Number (if known)

K232409

Device Name

Electromagnetic Stimulation Systems

Indications for Use (Describe)

The Electromagnetic Stimulation System 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.

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510(k) summary K232409

I Submitter

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Establishment Registration Number: 3007120647

Date of preparation: Feb 19th, 2024

Contact Person

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II Proposed Device

Trade Name of Device: Electromagnetic Stimulation Systems

Common name: Electromagnetic Stimulation Systems

Regulation Number: 21 CFR 890.5850

Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning

Regulatory Class: Class II

Product code: NGX

Review Panel: Physical Medicine

III Predicate Devices

510(k) Number: K200382

Trade name: BTL-703-2

Common name: BTL-703-2

Classification: Class II

Product Code: NGX

Manufacturer: BTL Industries, Inc.

IV Device description

The HS-591 Electromagnetic Stimulation System is a non-invasive therapeutic device which comprised of a main unit and applicators that deliver electromagnetic energy to the targeted tissue of adult patients.

The device is equipped with a color touch-screen that facilitates the use of the device. The on-screen information guides the user step-by-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.

V Indication for use

The Electromagnetic Stimulation System 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.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K200382)	Discussion
Product Code	NGX	NGX	Identical
Regulation No.	21 CFR 890.5850	21 CFR 890.5850	Identical
Class	Class II	Class II	Identical
Indication for use	<p>The Electromagnetic Stimulation System is indicated to be used for:</p> <ul style="list-style-type: none"> ● 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. 	<p>The Electromagnetic Stimulation System is indicated to be used for:</p> <ul style="list-style-type: none"> ● 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. 	Identical
Principle of Action	Electromagnetic stimulation	Electromagnetic Stimulation accompanied by bipolar radiofrequency	Different
Clinical Use	Prescription use	Prescription use	Identical

Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Identical
Electrical Protection	Class I, BF	Class II, BF	Different
User Interface	Touch screen	Touch screen	Identical
Firmware Controlled	Yes	Yes	Identical
Type of Energy	Magnetic field	Magnetic field	Identical
Number of outputs	4	2	Different
Number of magnetic coils	1	1	Identical
Maximum Magnetic Field Intensity at Applicator Center Surface	1.2 Tesla	BTL-899-AP-C-1 applicator: 908mT BTL-899-AP-C-2 applicator: 1238mT	Similar
Magnetic Field Intensity on the coil surface	0.46-1.38T	BTL-899-AP-C-1 applicator: 0.5-1.8T BTL-899-AP-C-2 applicator: 0.7-2.0T	Similar
Pulse Repetition Rate	1~100Hz	1 – 150 Hz	Similar
Pulse Duration	330µs	BTL-899-AP-C-1 applicator: 280 ± 20% µs BTL-899-AP-C-2 applicator: 190 ± 20% µs	Similar
Selection of parameters (Intensity, Time)	Yes	Yes	Identical
Energy Source	110~240V, 50/60Hz	100 – 240 V AC, 50–60 Hz	Identical
System Dimensions (W×H×D)	580×650×1520mm	592×985×730 mm (23×39×29 in)	Similar
Ambient Temperature	-40°C to +55°C	-10°C to +55°C	Similar
Relative Humidity	Up to 93%	10% to 85%	Similar
Environmental Specifications	For indoor use only	For indoor use only	Identical

VII Non-Clinical Testing

A series of tests have been performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

- IEC 60601-1 : 2005+A1 : 2012+A2 : 2020 / EN 60601-1: 2006+A1: 2013+A12:2014+A2:2021 Medical electrical equipment. General requirements for basic safety and essential performance
- IEC60601-1-2:2014+A1:2020 / EN 60601-1-2:2015+A1:2021 Medical electrical equipment - part 1-2 General requirements for basic safety and performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 62304:2006+AMD1:2015 Medical device software - Software life cycle processes

Biocompatibility Evaluation:

Per FDA's Biocompatibility Guidance issued on September 04, 2020 and with regard to Table A.1 Evaluation Tests for consideration in ISO, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" " the following tests performed on the material which contacts with human for Biocompatibility:

- Cytotoxicity;
- Skin irritation;
- Skin Sensitization.;

VIII Clinical Testing

It is not applicable.

IX Conclusion

Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.