November 25, 2024

Shandong Huamei 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, Beijing 102401
China

Re: K232982
Trade/Device Name: EMS Sculpt Machine
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 25, 2024
Received: March 25, 2024

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
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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)*
K232982

Device Name
EMS Sculpt Machine

Indications for Use *(Describe)*
The EMS Sculpt Machine 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 and thighs.

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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510(k) Summary
K232982

Date of Preparation: 09/15/2023

Sponsor Identification

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Device:

Trade name: EMS Sculpt Machine
Common name: Powered muscle stimulator

Regulatory Information

Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning
Classification: Class 2
Product Code: NGX
Regulation Number: 21 CFR 890.5850
Regulation Name: Stimulator, Muscle, Powered, For Muscle Conditioning
Review Panel: Physical Medicine

Predicate Device(s)

Primary Predicate Device
510(k) Number: K163165
Product Name: AM-100
Manufacturer: BTL Industries, Inc.
Classification: Class 2
Product Code: NGX
Regulation Number: 21 CFR 890.5850

Indication For Use Statement:

The EMS Sculpt Machine 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 and thighs.

Device Description

The EMS Sculpt Machine is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. By muscle stimulation, the EMS Sculpt Machine helps to strengthen and firm the abdomen, buttocks and thighs.

The EMS Sculpt Machine is equipped with a LCD touch screen that significantly facilitates the use of the device. The user exchanges with the system by the LCD and the keys on it. The state of the system, the operation interface, the instructions and hints to the user will be shown on the LCD.

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:

- ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility- 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

Clinical Test Conclusion

No clinical study is included in this submission.

Technological Characteristics

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device (K163165)	Remark
Indications for use	The EMS Sculpt Machine 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 and thighs.	AM-100 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 and thighs.	SAME
Product Code	NGX	NGX	SAME
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	SAME
Regulation Name	Stimulator, Muscle, Powered, For Muscle Conditioning	Stimulator, Muscle, Powered, For Muscle Conditioning	SAME
Classification	II	II	SAME
Prescription vs. OTC	Prescription use	Prescription use	SAME
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	SAME
User Interface	Touch screen	Touch screen	SAME
Type of Energy	Magnetic field	Magnetic field	SAME
Firmware Controlled	YES	YES	SAME
Environmental Specifications	For indoor use only	For indoor use only	SAME
Magnetic Field Intensity	HM-P handle:0.1-2.5T HM-C handle:0.1-2T	Applicator 299-1: 0.5–1.8 T Applicator 299-2: 0.7–2.5 T	Analyze 1
Type of Operation	Continuous	Continuous	SAME
Pulse Frequency	1-150Hz	1-150Hz	SAME
Pulse Duration	280 ± 20% μs	280 ± 20% μs	SAME
Pulse Amplitude	0-100%	0 – 100%	SAME
Induced Current in the Tissue	28-30mA	28-30 mA	SAME
Selection of parameters (Intensity, Time)	YES	YES	SAME
Therapy Time	Up to 30 min	Up to 60 min	Analyze 2
Shape of Stimulation Pulse	Bidirectional wave	Bidirectional wave	SAME

Energy Source	100~240VAC,50/60Hz	100 – 240 VAC, 50–60 Hz	SAME
System Dimensions (W×H×D)	497.5×1109×615mm	500×970×580 mm (20×38×23 in)	Analyze 3
Ambient Temperature	-10℃~55℃	-10°C to +55°C	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	NA	Analyze 4
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

Analyze 1：

The Magnetic Field Intensity of subject device is 0.1-2.5T, The max Magnetic Field Intensity is same to the predicate device and no new risk arises. 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 effective, both the proposed device and predicate device are safe and effective.

Analyze 2：

The treatment of proposed device is between 0~30 min, it is less than predicate device. The high temperature risk is lower than predicate device. Both of them meet the requirements of IEC 60601-1and IEC 60601-2-10, so we believe that this difference will not raise any risks in safety and effective, both the proposed device and predicate device are safe and effective.

Analyze 3：

The proposed device is different in System Dimensions from the predicate device. However, the configuration difference is 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 of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 4:

The proposed device is different in Biocompatibility Testing Standard from the predicate device (K163165). 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.

Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K163165).