September 6, 2023

Beijing Sano Laser S&T Development Co., Ltd
% Heather Wang
Consultant
Microkn Medical Technology Service (Shanghai) Co.,Ltd.
Room 901, No. 889, Pinglu Road, Jing'an District
Shanghai (Shanghai Jing'an HUAFA Center)
Shanghai, 200435
China

Re: K230024
Trade/Device Name: HI-EMT MAGSHAPE
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 25, 2023
Received: July 25, 2023

Dear Heather 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230024

Device Name
HI-EMT MAGSHAPE

Indications for Use *(Describe)*

- 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
K230024

1. Contact information

1.1. Applicant

Applicant Name: Beijing Sano Laser S&T Development Co., Ltd.

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Date prepared: Dec. 15, 2022

1.2. Consultant

Company: Microkn Medical Technology Service (Shanghai) Co.,Ltd.

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Contact Person: Heather. Wang

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Email: heather.wang@microkn.com

2. Device information

- Trade Name: HI-EMT MAGSHAPE
- Classification Name: Stimulator, Muscle, Powered, for Muscle Conditioning
- Model(s): SHE-MSP003, SHE-MSP002, SHE-MSP001
- Classification: II
- Product Code: NGX
- Regulation Number: 21 CFR 890.5850

3. Indications for Use

- 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.

4. Legally Marketed Predicate Device

Product name: BTL 799-2L

510(k) Number: K190456

Product Code: NGX

Manufacture: BTL Industries, Inc.

5. Description of the device

The proposed device is a type of the most advanced electromagnetic,non-invasive treatment machine (with attachments). It is used for muscle

tension enhancement and muscle strengthening on abdomen, hips, thighs, arms, etc.

Three models (SHE-MSP003, SHE-MSP002 and SHE-MSP001) are included in HI-EMT MAGSHAPE series products, and they have the same intended purposes, working theories and specifications.

The main components of proposed device shown in **Table 1**.

Table 1 Main Components of Proposed Device

Components	Functions	Applied to
Handle	Deliver Electromagnetic Field Energy to Body Part to be Treated	ALL Models
Color Touch Screen	User Interface and System Used for Control	ALL Models
Air Switch	Protect the System	ALL Models
KEY Switch	Start the System	ALL Models

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 Medical electrical device Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

The HI-EMT MAGSHAPE has been carefully compared to legally marketed devices with respect to intended use, configuration, principle of operation **(Table 2)**, performance specifications **(Table 3)**.

Table 2 General Comparison

Item	Proposed Device	Predicate Device	Remark
	HI-EMT MAGSHAPE K230024	**BTL 799-2L K190456**	
Product Code	NGX	NGX	Same
Regulation Number	21CFR 890.5850	21 CFR 890.5850	Same
Indications for Use	• Improvement of abdominal tone, strengthening of the	• Improvement of abdominal tone, strengthening of the	Same

Item	Proposed Device	Predicate Device	Remark
	HI-EMT MAGSHAPE	**BTL 799-2L**	
	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.	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.	
Principle of Operation	Initiating action potential of nerves results in muscle contraction.	Initiating action potential of nerves results in muscle contraction.	Same
Type of use	Prescription use	Prescription use	Same

Table 3 Performance Comparison

Item	Proposed Device	Predicate Device	Remark
	HI-EMT MAGSHAPE	**BTL 799-2L**	
Electronic Protection Class	Class I, Type B	Class II, Type BF	Similar Note 1
User Interface	Touch screen	Touch screen	Same
Type of Energy	Magnetic field	Magnetic field	Same
Magnetic Field Intensity	0-2 T	BTL 299-6 applicator: 0.5 - 1.8 T±20% BTL 299-7 applicator: 0.7 - 2.0 T±20%	Similar Note 2
Pulse Repetition Rate	F1:1-10Hz F2:1-100Hz	1-150 Hz	Similar Note 2
Pulse Duration	300 μ s	BTL 299-6 applicator:	Similar Note 2

Item	Proposed Device	Predicate Device	Remark
	HI-EMT MAGSHAPE	BTL 799-2L	
		280 ±20% μs	
		BTL 299-7 applicator: 190 ±20% μs	
Selection of parameters (Intensity, Time)	Yes	Yes	Same
Therapy Time	Up to 60 min	Up to 60 min	Same
Energy Source	AC110V, 60Hz	100-240 V AC, 50-60 Hz	Similar Note 1
System Dimensions (D × W × H)	MSP001: 520 * 440 * 1240mm, Tolerance: ≤±5% MSP002: 530 * 400* 1140mm, Tolerance: ≤ ±5% MSP003: 550 *	580 × 580 × 1380 mm (23 × 23 × 55 in)	Similar Note 3

Item	Proposed Device	Predicate Device	Remark
	HI-EMT MAGSHAPE	**BTL 799-2L**	
	400 * 1140mm, Tolerance: ⩽ ±5%		
Ambient Temperature	+ 16℃ ~ + 35℃	-10 ° C ~ + 55 ° C	Similar Note 4
Relative Humidity	80%, No Condensation	10% to 85%	Similar Note 4
Environmental Specifications	For indoor use only	For indoor use only	Same

Note 1

The proposed device HI-EMT MAGSHAPE has minor difference on Electronic Protection Class and Energy Source with the predicate device BTL 799-2L, but the proposed device had passed IEC 60601-1 and IEC 60601-1-2 test codes, so these differences don't raise any new safety and effectiveness issues.

Note 2

The proposed device HI-EMT MAGSHAPE has differences on stimulation parameter with the predicate device BTL 799-2L. The differences do not raise new question of safety and or effectiveness.

Note 3

The proposed device HI-EMT MAGSHAPE has minor difference on System Dimensions with the predicate device BTL 799-2L, but differences on appearance design will not affect the effectiveness and performance of the product and will not increase the risk of the product. So, it doesn't raise any new safety and effectiveness issues.

Note 4

The proposed device HI-EMT MAGSHAPE has minor difference on Ambient Temperature and Relative Humidity with the predicate device BTL 799-2L, but the proposed device had passed the accelerated aging test, so the difference won't raise any new safety and effectiveness issues.

Safety comparison has been done to validate the EMC specification and safety of the device (Table 4).

Item	Proposed Device	Predicate Device	Remark
Electrical safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Biocompatibility Consideration:

The skin contacting element is Acrylonitrile butadiene styrene (ABS). The biocompatibility of the device was assessed in accordance with FDA's 2020 Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'"

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.