March 9, 2023

Nanjing Vishee Medical Technology Co., Ltd.
Lisa Tan
Regulatory Affairs
Building 9, No. 19, Ningshuang Road
Yuhuatai District
Nanjing, Jiangsu 210012
China

Re: K222875
Trade/Device Name: Powered Muscle Stimulator (Model name: MagGraver F200)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 15, 2022
Received: September 22, 2022

Dear Lisa Tan:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222875

Device Name
Powered Muscle Stimulator (Model name:MagGraver F200)

Indications for Use *(Describe)*
Powered Muscle Stimulator (Model name:MagGraver F200) 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.

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: March 08,2023

1. Submitter's Information

OFFICIAL CORRESPONDENT

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2. Device Identification

510(K) number:	K222875
Trade/Device Name:	Powered Muscle Stimulator
Models:	MagGraver F200
Common name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Number:	21 CFR 890.5850
Regulation Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Class:	Class 2
Panel:	Physical Medicine
Product Code:	NGX

3. Predicate Device

510(K) number:	K180813
Device Name:	BTL 799-2
Manufacturer:	BTL Industries, Inc.
Common name	Stimulator, Muscle, Powered, For Muscle Conditioning

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

4. Indication for Use

Powered Muscle Stimulator (Model name:MagGraver F200) 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.

5. Device Description

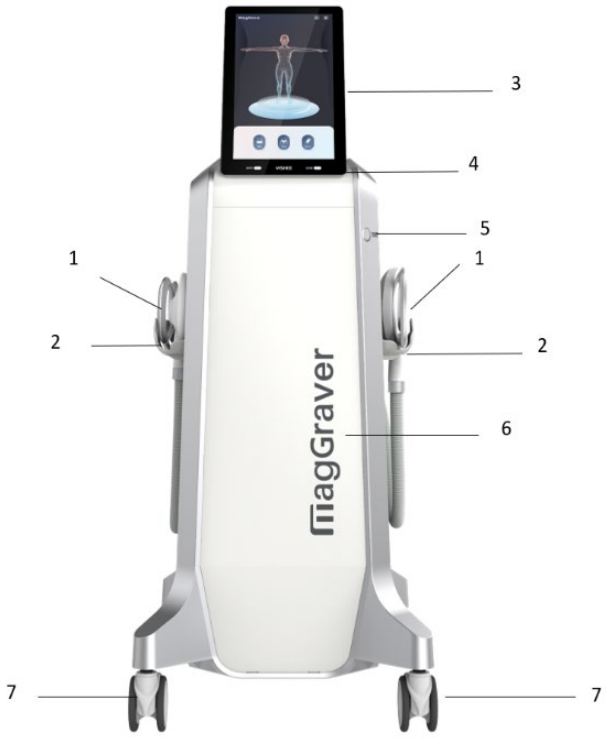
Powered Muscle Stimulator (Model name:MagGraver F200) is a non-invasive therapeutic device. The device produces electromagnetic field that stimulates the tissues of the human body, the device helps to strengthen, tone, and firm the abdomen and buttocks by stimulating muscle.

The device has two output channels and two applicators, one applicator (Form A) is applicable for abdomen and another (Form B) is applicable for buttocks. The applicator can plug in either output channels. The two outputs of device enable simultaneous treatment by two applicators.

The Form A applicator consists of round coil and cooling system. The Form B applicator consists of figure-of-eight coil and cooling system.

There is a pressure kit is used to monitor abdomen muscle contraction by monitor the pressure between applicator and abdomen, the pressure kit is only used with Form A applicator.

The device is equipped with a color touch screen that significantly 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. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen. The screen angle can be adjusted.

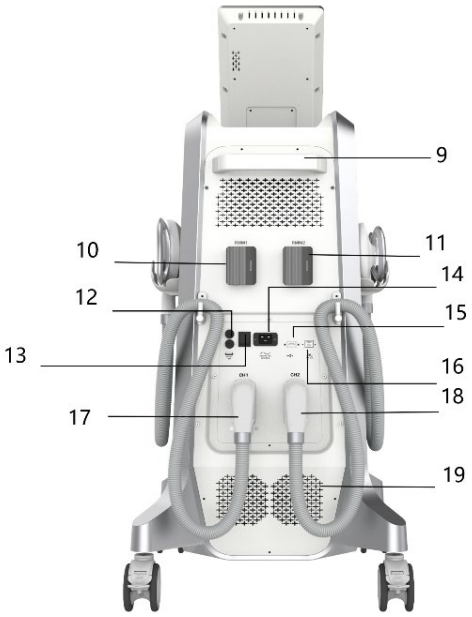


No.	Description
1	Applicators
2	Applicator holder hook
3	Touch screen
4	Indicator light
5	Power button
6	Trademark
7	Castors

Figure 1 Front of Powered Muscle Stimulator

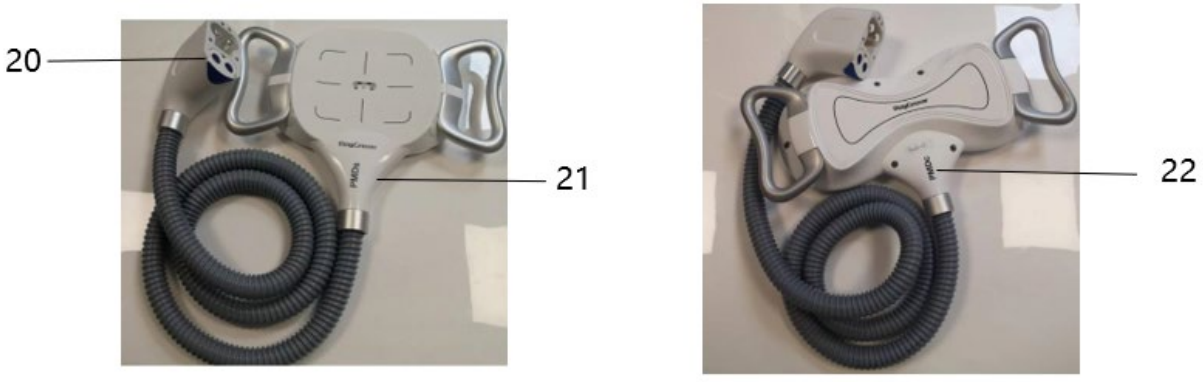
No.	Description
1	Applicators
2	Applicator holder hook
8	Emergency button

Figure 2 Right of Powered Muscle Stimulator



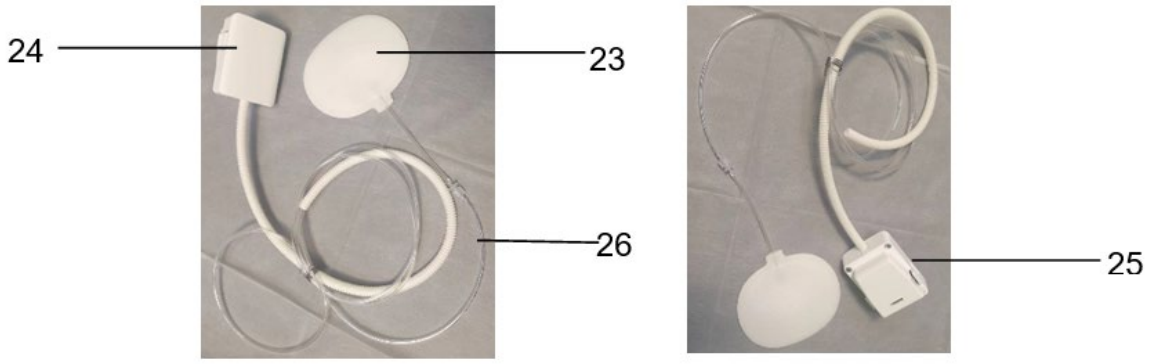
No.	Description
9	Handrail
10	Pressure kit interface (RMM1)
11	Pressure kit interface (RMM2)
12	Fuse socket
13	Main switch
14	Power inlet
15	USB Port
16	Network interface
17	Applicator interface (CH1)
18	Applicator interface (CH2)
19	Ventilation grid

Figure 3 Back of Powered Muscle Stimulator



20: Spring lock latch, 21: Applicator (Form A), 22: Applicator (Form B)

Figure 4 Applicator



23: Pressure airbag, 24: Pressure control device, 25: Snap lock (button-type),26: Air hose

Figure 5 Pressure kit

6. Compared to Predicate Device

Compared to the predicate devices, the subject device has the similar intended use, similar product design, similar performance, same safety as the predicate device, the summarized comparison information is listed in the following table

SE Comparisons	**Subject Device** Powered Muscle Stimulator (Model name:MagGraver F200) (K222875)	**Primary Predicate Device** BTL 799-2 (K180813)	**Similarities/ Differences**
Indication for Use	Powered Muscle Stimulator (Model name:MagGraver F200) 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.	BTL 799-2 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.	See Note 1
Product code	NGX	NGX	Same
Class	II	II	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
User Interface	Touch screen	Touch screen	Same
Type of Energy	Magnetic field	Magnetic field	Same

SE Comparisons	**Subject Device** Powered Muscle Stimulator (Model name:MagGraver F200) (K222875)	**Primary Predicate Device** BTL 799-2 (K180813)	**Similarities/ Differences**
Number of outputs	2	2	Same
Number of Magnetic Coils in the Applicator	1	1	Same
Magnetic Field Intensity	Form A applicator: 0–1.8 T Form B applicator: 0–1.8 T	299-6 applicator: 0.5–1.8 T	Note 2
Pulse Repetition Rate	1-150Hz	1-150Hz	Same
Pulse Duration	340 μs ±20 μs	280±20% μs	Note 3
Pulse Amplitude	0-100%	0-100%	Same
Selection of parameters (Intensity, Time)	YES	YES	Same
Therapy Time	Up to 36 min	Up to 60 min	Note 4
Power rate	100-240 VAC,50-60Hz, 2.5kVA	100-240 VAC, 50-60 Hz,2800W	Note 5
System Dimensions (W×H×D)	576 (L) × 669 (W) × 1100 (H) mm	500×1380×580 mm (20×55×23 in)	Note 5
Operation condition	+5°C to +28°C ⩽ 80% RH 860hPa to 1060hPa	+10°C to +30°C 30% to 75% RH 700hPa to 1060hPa	Note 5
Transport and storage conditions	-20°C to +55°C ⩽ 80% RH 860 hPa to 1060 hPa	-10°C to +55 °C 10% to 85% RH 650 hPa to 1100 hPa	Note 6
Environmental Specifications	For indoor use only	For indoor use only	Same

Note 1: The proposed device is not intended use for thighs.

Note 2: The Magnetic Field Intensity of subject device is 0-1.8T, no new risk arises.

Note 3: There have been theoretical studies presented that only relatively small variations in the average recruited nerve fiber diameter of approximately 1 μ m were observed in the experimental study, when the stimulus pulse width was increased from 50 μ s to 500 μ s. The theoretical prediction of the relatively small variation in motor nerve fiber recruitment patterns coupled with consistent experimental evidence suggests that there is little potential for achieving significant motor nerve fiber

recruitment selectivity by varying the stimulus pulse width over the clinically useful range of 50 μ s to 500 μ s when surface stimulation is used [1]. The pulse width of the subject device and the predicate device are in the typical clinical range of 50 to 500 μs, the difference will not affect product safety and performance.

Note 4: The treatment of proposed device is between 0~36 min, it is less than subject device. The high temperature risk is lower than predicate device.

Note 5: The subject device complies with IEC 60601-1: 2005+A1:2012, no energy risk and mechanical risk arise. And the subject device can be operated in operation conditions manufacture specified.

Note 6: We conducted simulate transportation tests, the subject device can be transported and stored in transport and storage conditions manufacture specified.

The subject device and predicate devices are substantially equivalent in the areas of technological characteristics such as basic design, features, energy source, method of operation, general function, application, and intended use. The subject device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

-Safety

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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

-EMC

IEC 60601-1-2:2014 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic Disturbances-Requirements and tests

-Biocompatibility

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

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[1] *Szlavik RB, de Bruin H. The effect of stimulus current pulse width on nerve fiber size recruitment patterns. Med Eng Phys. 1999 Jul-Sep;21(6-7):507-15. doi: 10.1016/s1350-4533(99)00074-0. PMID: 10624746*

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

-Shelf life

Internal test method.

-Simulated transportation

ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

-Software Verification and Validation:

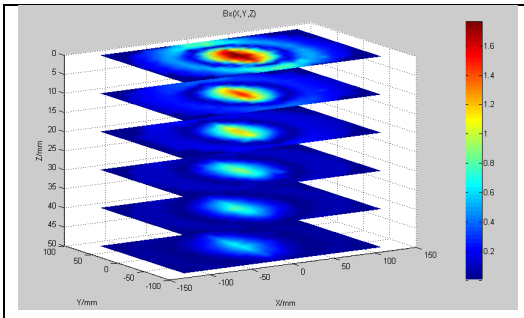
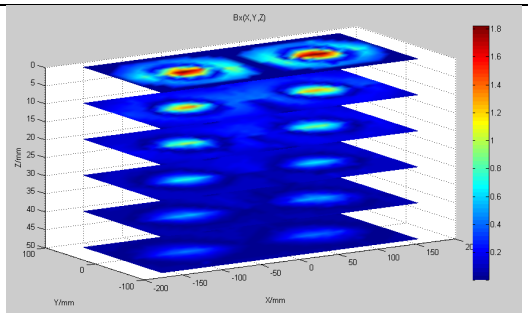
Software 2021 draft Content of Premarket Submissions for Premarket-Software-Functions-Guidance

Performance Testing:

-Bench Testing

a.Take the center of the applicator as the starting point (0, 0, 0), and the distance between each target point is 10mm, measure the pulse waveform of the target point. The X-axis of Form A has a range of [-120, 120], the Y-axis has a range of [-80, 80], and the Z-axis has a range of [0, 50]. The X-axis of Form B has a range of [-80, 80] for each side of figure 8 coil, the Y-axis has a range of [-80, 80], and the Z-axis has a range of [0, 50], as shown below. Record the maximum magnetic induction intensity at each point and save the pulse waveform. The measured data was mapped into a three-dimensional magnetic field distribution map with F-30 multi-dimensional magnetic field analysis system manufactured by CH-Magnetoelectricity Technology.

Test results show dB/dt is 34.04KT/s, the magnetic field mapping see below photo:

	
Magnetic field distribution of FORM A	Magnetic field distribution of FORM B

b. Applied to the stimulation applicator, the Tesla meter probe is placed vertically on the central position surface of the stimulation applicator, and the maximum value measured is the maximum magnetic induction intensity of the stimulation applicator.

The test results show Form A applicator Magnetic Intensity is 1.8T,Form B applicator Magnetic Intensity is 1.8T.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device (K180813).