July 7, 2023

Beijing ADSS Development Co., Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K231318
Trade/Device Name: Electromagnetic Stimulator Device (Models: EM Contouring and Tesla Duet)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 8, 2023
Received: May 8, 2023

Dear Mr. Boyle 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

Digitally signed by Tushar Bansal -S
Date: 2023.07.07 14:27:15 -04'00'

for Heather Dean, Ph.D.
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

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)*
K231318

Device Name
Electromagnetic Stimulator Device (Model: EM Contouring, Tesla Duet)

Indications for Use *(Describe)*
The device 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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 submitter's Information

Name: Beijing ADSS Development Co., Ltd.
Applicant Address: Room 609, F6, Building 13, Yard 5 Tianhua Street, Daxing District, Beijing, 102600, P. R. China
Production Address: Fuda Road - Tongsheng Road, Southern Area of Industrial Park,Gu'an County, 065599 Langfang City, Hebei Province, P.R. China
Tel: 86-13051615111
Contact: Song Ying

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: May.5th,2023

2.0 Device Information

Trade name: Electromagnetic Stimulator Device
Common name: Powered muscle stimulator
Classification name: Stimulator, Muscle, Powered, For Muscle Conditioning
Model(s): EM Contouring, Tesla Duet
Production code: NGX
Regulation number: 21CFR 890.5850
Classification: Class II
Panel: Physical Medicine

3.0 Predicate and Reference Devices

Predicate Device:

Manufacturer: BTL Industries, Inc.

Device: BTL 799-2
510(k) number: K180813

Reference Device：

Manufacturer: BTL Industries, Inc.
Device: BTL 799-2L
510(k) number: K190456

4.0 Device Description

The Electromagnetic stimulator device consists of a host, hand tools and power cord. The host contains a power supply unit, a control unit, and a cooling unit. The control unit includes a control element and a liquid crystal display. The hand tools include electromagnetic induction coils and cooling fans, it is a non-invasive therapeutic device.

The subject device has two models, Tesla Duet and EM contouring. The two models are exactly the same except for the color of the host shell, one is black and other is white.

The device produces electromagnetic field that interacts with the tissues of the human body. By muscle stimulation, the Electromagnetic stimulator device helps to strengthen, tone and firm the abdomen, buttocks and thighs. The device two outputs enable simultaneous treatment by two applicators.

The Electromagnetic stimulator device is equipped with a large color touch screen with wide view angle 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 and buttons on the device. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

5.0 Indication for Use Statement

The device 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.

6.0 Comparison to the Predicate Device

Table 6.1: Technological Characteristics between Subject and Predicate Device

Item	Subject Device	Predicate Device	Reference Device	Comparison
Manufacturer	Beijing ADSS Development Co., Ltd.	BTL Industries, Inc.	BTL Industries, Inc.	——
510(k) No.	K231318	K180813	K190456	——
Trade name	Electromagnetic Stimulator Device	BTL 799-2	BTL 799-2L	——
Model	EM Contouring, Tesla Duet	BTL 799-2	BTL 799-2L	——
Regulation number	21 CFR 890.5850	21CFR 890.5850	21CFR 890.5850	Same
Regulation Name	Powered muscle stimulator	Powered muscle stimulator	Powered muscle stimulator	Same
Product code	NGX	NGX	NGX	Same
Class	II	II	II	Same
Indications for use/Intended use	The device 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.	BTL 799-2L 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.	Same

	and thighs.		• Improvement of muscle tone and firmness, for strengthening muscles in arms.	
Location for use	Prescription Use	Prescription Use	Prescription Use	Same
Primary Function	Muscle stimulation	Muscle stimulation	Muscle stimulation	Same
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Same
Electrical Protection	Class II, BF	Class II, BF	Class II, BF	Same
User Interface	Touch screen	Touch screen	Touch screen	Same
Touch screen size	15.6" (39.6 cm)	15.6" (39.6 cm)	15.6" (39.6 cm)	Same
Firmware Controlled	Yes	Yes	Yes	Same
Type of Energy	Magnetic field	Magnetic field	Magnetic field	Same
Number of outputs	2	2	2	Same
Number of Magnetic Coils in the Applicator	1	1	1	Same
Number of Magnetic coils	1	1	1	Same

in the Applicator				
Applicator Dimensions	252.3*167.3*96mm(± 0.2mm)	Not publicly available	Not publicly available	——
Surface Area	Surface Area of the Treatment probe:13471.4mm² Surface Area of the Applicator: 33257.7mm²	Not publicly available	Not publicly available	——
Magnetic Field Intensity (on the coil surface)	0.5-1.8T,±20%	299-6 applicator: 0.5–1.8 T	BTL 299-6 applicator: 0.5 - 1.8 T ,±20% BTL 299-7 applicator: 0.7 - 2.0 T ,±20%	Same
Maximum Magnetic Field Intensity at Applicator Center Surface	1.0T±20%	BTL 299-6 applicator: 1.154 T±20%;	BTL 299-6 applicator: 1.154 T±20%; BTL 299-7 applicator: 1.173 T±20%.	The maximum field intensity at Applicator Center Surface is 1.0T as compared to the 1.154T of the predicate device. However, the magnetic field intensity is within the range of the predicate device.
Induced Current in the Tissue	20.6mA	28-30 mA	Not publicly available	The induced current on the tissue for the subject device is less than the predicate device and therefore safer with the same effect.
Type of Operation	Continuous	Continuous	Continuous	Same

Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz	Same
Pulse Duration	270 ±20% µs	280 ± 20% µs	BTL 299-6 applicator: 280 ± 20% µs; BTL 299-7 applicator: 190 ± 20% µs	The subject device has little shorter pulse width when compared to the predicate device but in the range between the predicate and reference device.
Pulse Amplitude	0 – 100%, step 1%	0 – 100%	Not publicly available	Same
Selection of parameters (Intensity, Time)	Yes	Yes	Yes	Same
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	Same
Therapy Time	1-60min	Up to 60 min	Up to 60 min	Same
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Same
Energy Source	100–240 VAC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	Same
System Dimensions (W×H×D)	525×433×1279mm/ 640×560×1390mm	500×1380×580 mm (20×55×23 in)	580×1380×580 mm (23×55×23 in)	Different dimensions have no influence on the safety or effectiveness of the device.
Ambient Temperature	-20℃～+55℃	-10°C to +55°C	-10°C to +55°C	This difference has no influence on the safety or effectiveness of the device.

Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	Same
Conformance Standard	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-1-9; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-2-10	Same
Patient contact material	Hand Tool: ABS&PC	Not publicly available	Not publicly available	Biocompatibility evaluation for both the subject device and the predicate device. The difference does not affect safety and effectiveness.
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

7.0 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject devices met all design specifications as were Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) 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
- IEC60601-2-10:2016, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-6: 2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-9:2007+A1:2013, Medical electrical equipment- Part 1-9: General requirements for basic safety and essential performance Collateral Standard: Requirements for environmentally conscious design
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Software Information:
Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

8.0 Clinical Test Conclusion

No clinical study is included in this submission.

9.0 Conclusion

Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. And based on the performance testing and compliance with acceptable voluntary standards, we believe the subject device is substantially equivalent to its predicate device.