April 24, 2024

Hebei JT Medical Co., Ltd.
% Gina Lian
General Manager
Beijing STYH Medical Technology Service Co. Ltd.
No.18, Jianshe Road, Kaixuan Street, Liangxiang Town,
Fangshan District,
Beijing, Beijing 102488
China

Re: K232181
Trade/Device Name: Body Contouring Machine (Models: CS2, CS3, CS5, CS7, CS8, CS11, CS13)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: August 7, 2023
Received: August 9, 2023

Dear Gina Lian:

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,

Tushar Bansal -S

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

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)*
K232181

Device Name
Body Contouring Machine (Models: CS2, CS3, CS5, CS7, CS8, CS11, CS13)

Indications for Use *(Describe)*
Body Contouring Machine can be used to:
- 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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510k Summary
K232181

510(k) Summary

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

The assigned 510(k) Number: **K232181**

1. Date of Preparation

   8/7/2023

2. Sponsor

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3. Submission Correspondent

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4. Identification of Subject Device

Trade Name: Body Contouring Machine
Common Name: Stimulator, muscle, powered, for muscle conditioning
Model(s): CS2,CS3,CS5,CS7,CS8,CS11,CS13

Regulatory Information:
Classification Name: Stimulator, muscle, powered, for muscle conditioning
Classification: II;
Product Code: NGX;
Regulation Number: 21 CFR 890.5850 ;
Review Panel: Physical Medicine ;

Indication for Use:
Body Contouring Machine can be used to:

- ✓ 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.

5. Device Description

Body Contouring Machine is a non-invasive treatment device. The device generates an electromagnetic field that interacts with human tissue. Body Contouring Machine is equipped with four handles, two each for ZH-01 and ZH-03, which can treat different parts of the body at the same time. The device is equipped with a 15.6-inch true-color touch screen and provides two operating modes, intelligent and professional, to meet the different needs of users.

The Body Contouring Machine includes seven models in this submission, CS2,CS3,CS5,CS7, CS8,CS11, and CS13, all seven models have same principle, software, operation etc., only differences are appearance

The subject device includes the following components:

Table 1 Main Components of Subject Device

Components	Function Description	Applied Model(s)
1.Handle	The handle is the working component of the treatment. Perform treatment according to the treatment parameters set by the host.	CS2、CS3、CS5、CS7、CS8、CS11、CS13
2.LCD screen	The device is equipped with a 15.6-inch true color touch screen.	CS2、CS3、CS5、CS7、CS8、CS11、CS13
3.Emergency	In an emergency, press this button to disconnect the	CS2、CS3、CS5、CS7、

stop switch	control system and power supply, rotate it to the right and eject the button to return to normal.	CS8、CS11、CS13
4.Casters	Push the equipment horizontally to the designated position	CS2、CS3、CS5、CS7、CS8、CS11、CS13
5.Push button switch	press this button under normal circumstances to open and close the control system and power supply	CS2、CS3、CS5、CS7、CS8、CS11、CS13
6.Handle bracket	fixed treatment handle	CS2、CS3、CS5、CS7、CS8、CS11、CS13

6. Identification of Predicate Device

Predicate device 510(k) number: K190456
Trading name: BTL 799-2L
Common name: Stimulator, muscle, powered, for muscle conditioning
Regulation No.: 21 CFR 890.5850
Classification name: Stimulator, muscle, powered, for muscle conditioning
Classification: Class II
Product code: NGX

7. Non-Clinical Test Conclusion

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

- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- IEC 60601-2-10:2012/AMD2:2023 Medical electrical equipment Part 2:Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
- IEC62304:2015, Medical device software – Software life cycle processes
- ISO 14971:2019, Medical devices – Application of risk management to medical devices
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and

testing within a risk management process

- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization
- Magnetic density test.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

ITEM	Subject Device	Predicate Device
Product Code	NGX - Stimulator, Muscle, Powered, Muscle Conditioning	NGX - Stimulator, Muscle, Powered, Muscle Conditioning
Regulation Number	21 CFR 890.5850	21 CFR 890.5850
Regulatory Class	Class II	Class II
Clinical Use	Prescription use	Prescription use
● Indication for Use	Body Contouring Machine can be used to: ● 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.	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. ● Improvement of muscle tone and firmness, for strengthening muscles in arms.
ITEM	**Subject Device**	**Predicate Device**
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction.
Electrical Protection	Class II, BF	Class II, BF
User Interface	Touch screen	Touch screen
Firmware Controlled	Yes	Yes
Type of Energy	Magnetic field	Magnetic field
Number of outputs	4	2
Number of Magnetic Coils in the Applicator	1	1
Magnetic Field Intensity	ZH-01 applicator: 0.1-1.8T±20%	BTL 299-6 applicator: 0.5 - 1.8 T ±20%
	ZH-03 applicator: 0.1-2.5T±20%	BTL 299-7 applicator: 0.7 - 2.0 T ±20%

Pulse Repetition Rate	1-150Hz	1 – 150 Hz
Pulse Duration	300±20 μs	BTL 299-6 applicator: 280 ± 20% μs
	190±20 μs	BTL 299-7 applicator: 190 ± 20% μs
Selection of parameters (Intensity, Time)	Yes	Yes
Therapy Time	Up to 60 min	Up to 60 min
Energy Source	220/110V ,50 – 60 Hz	100 – 240 V AC, 50 – 60 Hz
System Dimensions (W×H×D)	450*530*1220mm	580×1380×580 mm (23×55×23 in)
Environmental Specifications	For indoor use only	For indoor use only
Patient Contacted Part	Skin	Skin

Table 4 Safety Comparison

Item	**Subject Device**	**Predicate Device**
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1, IEC 60601-2-10
	Comply with IEC 60601-2-10	Comply with IEC 60601-2-10
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

Analysis:

These difference between the predicate devices and subject device have no significant influence on safety or effectiveness of the Body Contouring Machine.

The subject device is substantially equivalent to the predicate device. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

10. Substantially Equivalent (SE) Conclusion

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