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: K240658
Trade/Device Name: 1060nm laser body slimming machine
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: March 3, 2024
Received: March 8, 2024

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,

for Yan Fu -S Digitally signed by Yan Fu -S
Date: 2024.05.13 14:09:57 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240658

Device Name
1060nm laser body slimming machineModel: RZ-01

Indications for Use *(Describe)*
1060nm laser body slimming machine is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flank, back, 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K240658

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: __K240658__

1. Date of Preparation

   5/13/2024

2. Sponsor

HeBei JT Medical Co., Ltd.
C12 Hegu Industrial Park, Chaoyang Road, Development Zone ZhuoZhou city
Establishment Registration Number: Not yet registered or the Number
Contact Person: Karen Liu
Position: Sales manager
Tel: +86-13911459627
Fax:86-10-5721-2057
Email: 919309354@qq.com

3. Submission Correspondent

Ms. Gina Lian

Beijing STYH Medical Technology Service Co. Ltd.
No.18, Jianshe Road, Kaixuan Street, Liangxiang Town,
Fangshan District,102488 Beijing, China.
Tel: +86-13311543099
Email: 409308721@qq.com

4. Identification of Subject Device

Trade Name: 1060nm laser body slimming machine
Common Name: laser for disruption of adipocyte cells for aesthetic use;
Model(s): RZ-01

Regulatory Information:
Classification Name: laser for disruption of adipocyte cells for aesthetic use;
Classification: II;
Product Code: PKT;
Regulation Number: 21 CFR 878.5400 ;
Review Panel: General & Plastic Surgery ;

Indication for Use:
1060nm laser body slimming machine is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flank, back, and thighs.

5. Device Description

The 1060nm laser body slimming machine is an ultra-thermal laser fat decomposition system that uses the latest technology for non-invasive body shaping. It uses 1060nm wavelength laser penetration to target adipose tissue, selectively heats fat cells, and reduces the number of fat cells in the area through blood and lymph metabolism to achieve shaping the purpose of body contouring. It is a new generation of safe and effective way to lose weight.

Detailed description of cooling function
The handle head integrates a temperature sensor and skin contact sensor dual mechanism. The principle of the temperature sensor is based on the characteristic that the resistance of the NTC thermistor changes with the change of temperature, thereby achieving the measurement and monitoring of temperature. The principle of skin contact sensor is depending on whether it is in contact with the skin or not, the change signal of the resistance between the probes can be monitored to monitor the contact status with the skin.

The model of the 1060nm laser body slimming machine: RZ-01.

The subject device includes the following components:

Table 1 Main Components of Subject Device

Components	Function Description
1.Handle	The handle is the working component of the treatment. According to the treatment parameters set by the user, the treatment is carried out.
2.Screen	The device is equipped with a 15-inch true color touch screen.

3.Emergency stop switch	Press this button to disconnect the control system,and power supply in an emergency situation,turn right and eject the button to return to normal.
4.Casters	Push the equipment horizontally to the designated position.
5.Button switch	Start device work or stop device work.

6. Identification of Predicate Device

510(k) Number: K201731
Product Name: Diode Laser Body Sculpture System
Manufacturer: Shanghai Apolo Medical Technology Co., Ltd.

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 60601-1:2005+A1:2012+AMD2:2020,Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22：2019，Medical electrical equipment -Part 2-22: Particular requirements for the safety and essential performance of surgical,cosmetic, therapeutic and diagnostic laser equipment；
- 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 60825-1:2014 Safety of Laser products-Part 1:Equipment classification andrequirements；
- IEC60601-1-6:2010+A1:2013+A2:2020， Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability;
- IEC 62366-1:2015,Medical devices – Application of usability engineering to medical devices;
- IEC62304:2015，Medical device software – Software life cycle processes;
- ISO 14971:2019，Medical devices – Application of risk management to medical devices;
- ISO 10993-1:2020，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 10993-10:2021, Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization;
- ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation;

8. Clinical Test Conclusion

No clinical study is included in this submission.

Substantially Equivalent (SE) Comparison

Table 2 General Comparison

ITEM	Subject Device	Predicate Device （K 201731）	Discussion
Product Code	PKT - Laser for disruption of adipocyte cells for aesthetic use	PKT - Laser for disruption of adipocyte cells for aesthetic use	SE
Regulation Number	21 CFR 878.5400	21 CFR 878.5400	SE
Regulatory Class	Class II	Class II	SE
Clinical Use	Prescription use	Prescription use	SE
Indication for Use	1060nm laser body slimming machine is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.	The Diode Laser Body Sculpture Systems is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.	SE
User Interface	Touch screen	Touch screen	SE
Firmware Controlled	Yes	Yes	SE
Laser type	Diode laser	Diode laser	SE
Output Wavelength	1060nm	1060nm±20 nm	SE
Lipolysis method/Treatment regimen	Heat-assisted	Heat-assisted	SE
Spot size	4 * 8 cm^2	4 * 6 cm^2 /4 * 8 cm^2 on each of the Applicator heads (up to four applicators per body treatment)	SE
Pulse width/Output mode	CW	CW	SE

Irradiance	0.7W/cm² - 1.5W/cm²	0.8 ~ 1.6W/cm²	SE
Attachment to patient	Belt	Belt	SE
Peak power/Radiant power	50W (per applicator) for 4 * 8 cm²	35W (per applicator) for 4 * 6 cm² 50W (per applicator) for 4 * 8 cm²	SE
Cooling	Contact cooling	Contact cooling	SE

Table 4 Safety Comparison

Item	**Subject Device**	**Predicate Device**
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Laser Safety	Comply with IEC 60825-1	Comply with IEC 60825-1

Analysis1:

Although the power density values of subject device and predicate device are different, the power density values of subject device is within the range of the value of predicate device, and the safety and effectiveness of predicate device are verified, so the difference has no impact on the safety and effectiveness of subject device.

9. 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.