March 20, 2020

Beijing Lead Beauty S & T Co., Ltd
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120 Cn

Re: K193609
Trade/Device Name: Q Switched Nd: YAG Laser machine
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX,
Dated: December 16, 2019
Received: December 26, 2019

Dear Diana Hong:

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,

Jessica Mavadia-Shukla, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193609

Device Name
Q Switched Nd:YAG Laser machine

Indications for Use *(Describe)*

The Q-Switched Nd: YAG Laser Therapy System is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows:

1064nm:
-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.

532nm:
-Tattoo Removal
Light ink: red, Light ink: sky blue and green.
- Treatment of Benign Vascular Lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of Benign Pigmented Lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

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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Tab #6 510(k) Summary

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

The assigned 510(k) Number: K193609

1. Date of Preparation: 03/10/2020

2. Sponsor Identification

Beijing Lead Beauty S&T Co., Ltd.
202, No.5 workshop, No.1 caida 3rd Road Nancai Shunyi District, Beijing, China

Establishment Registration Number: Not registered

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
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Fax: 360-925-3199
Email: info@mid-link.net

510(k) Summary

4. Identification of Proposed Device

Trade Name: Q Switched Nd: YAG Laser machine
Common Name: Powered Laser Surgical Instrument
Model: QLHF-02

Regulatory Information

Classification Name: Powered Laser Surgical Instrument;
Classification: II;
Product Code: GEX;
Regulation Number: 21CFR 878.4810;
Review Panel: General& Plastic Surgery;

Indication for Use Statement:
The Q-Switched Nd: YAG Laser Therapy System is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows:

1064nm:
-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.

532nm:
-Tattoo Removal
Light ink: red, Light ink: sky blue and green.
- Treatment of Benign Vascular Lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of Benign Pigmented Lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

Device Description
The proposed device is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions. The device can produce two wavelengths, 1064nm and 532nm, to treat different skin color. It consists of control panel module, main control module, laser power module, temperature and humidity control module and laser module. The physician is able to select the desired wavelength and the related output energy via control panel.

510(k) Summary

5. Identification of Predicate Device

510(k) Number: K163123
Product Name: Q-Switched Nd:YAG Laser Systems
Manufacturer: Beijing Sincoheren Science and Technology Development Co., Ltd.

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 conforms with the following standards:

- 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.
- IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2-22:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

7. Clinical Test Conclusion

No clinical study is included in this submission.

510(k) Summary

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K163123
Product Code	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II
Indication for use	The Q-Switched Nd: YAG Laser Therapy System is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows: 1064nm: -Tattoo Removal Dark ink: blue and black. -Treatment of Benign Pigmented Lesions Nevus of ota. 532nm: -Tattoo Removal Light ink: red, Light ink: sky blue and green. - Treatment of Benign Vascular Lesions Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi. -Treatment of Benign Pigmented Lesions Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.	The Q-Switched Nd: YAG Laser Therapy System (1064nm or 532nm) is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows: 1064nm: -Tattoo Removal Dark ink: blue and black. -Treatment of Benign Pigmented Lesions Nevus of ota. 532nm: -Tattoo Removal Light ink: red, Light ink: sky blue and green. - Treatment of Benign Vascular Lesions Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi. -Treatment of Benign Pigmented Lesions Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.
Lamp Source	Xenon Lamp	Xenon Lamp
Energy Source	ND:YAG	ND:YAG
Laser Classification	Class 4	Class 4

510(k) Summary

Laser Wavelength	1064nm 532nm	1064nm 532nm
Max. Output Energy	500mJ for 1064nm 260mJ for 532nm	500mJ for 1064nm 250mJ for 532nm
Spot Size	2-10mm	2-10mm
Pulse Width	6ns±1ns	5ns±1ns or 5ns
Repetition Rate	1-10Hz	1-5Hz
Cooling method	internal distilled water circulating cooling	internal distilled water circulating cooling
Aiming beam wavelength	635nm	635nm
Aiming Beam	0.1mW-5mW	0.1mW-5mW
Laser output mode	Q-switched pulse	Q-switched pulse
Beam delivery	articulated arm light guide	articulated arm light guide
Patient contact material		
Light guide arm	Aluminum alloy	Steel, ABS
Biocompatibility		
Cytotoxicity	No Cytotoxicity	Conforms with ISO 19003
Sensitization	No evidence of Sensitization	
Irritation	No evidence of Irritation	
Electrical Safety and EMC		
Electrical Safety	Conforms with IEC 60601-1	Conforms with IEC 60601-1
EMC	Conforms with IEC 60601-1-2	Conforms with IEC 60601-1-2
Laser Safety	Conforms with IEC 60601-2-22, IEC 60825	Conforms with IEC 60601-2-22 IEC 60825

Electrical safety, EMC, and biocompatibility testing have been conducted on the proposed device, and the results show that the device conforms with the standards. The pulse width, repetition rate, and patient-contact material of the proposed device have differences compared to the predicate device. However, these differences do not substantially affect safety and effectiveness for the indications for use.

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.