April 13, 2020

Beijing Superlaser Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co, Ltd.
Rm. 912, Building #15, XiYueHui,
No. 5, YiHe North Rd., FangShan District
Beijing, 102401 CN

Re: K193464
Trade/Device Name: ND:YAG Laser
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: March 13, 2020
Received: March 16, 2020

Dear Ray 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,

Colin Kejing Chen
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)*
K193464

Device Name
ND:YAG Laser

Indications for Use *(Describe)*
The ND:YAG Laser is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.

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

The assigned 510(k) Number: K193464

1. Date of Preparation
   04/10/2020

2. Applicant

Name:	Beijing Superlaser Technology Co., Ltd.
Address:	No.2, Zhongfu Street, Economic and Technological Industrial zone, Xihongmen Tower, Daxing District, Beijing, China.
Contact Person:	Shi Shuang Position: Registration Specialist
Telephone:	86-10-81284899 ext. 806
Fax:	86-10-81284899
Email:	672257488@qq.com

3. Submission Correspondent
   Mr. Ray Wang
   Beijing Believe-Med Technology Service Co., Ltd.
   Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
   FangShan District, Beijing City, China, 102401
   Tel: +86-18910677558
   Fax: +86-10-56335780
   Email: ray.wang@believe-med.com

4. Identification of the Proposed Device

Trade Name:	ND:YAG Laser
Common Name:	Powered Laser Surgical Instrument
Model(s):	SL-NY602
Classification Name:	Powered Laser Surgical Instrument
Classification:	II
Product Code:	GEX
Regulation Number:	21 CFR 878.4810
Review Panel:	General& Plastic Surgery

5. Identification of Predicate Device

510(k) Number:	K161926
Product Name:	ND YAG Q-switch Laser Therapy Machine
Manufacturer:	Beijing ADSS Development Co., Ltd

6. Device Description
   The ND YAG Q-switch Laser Therapy Machine is laser system which delivers laser at a wavelength 1064nm or 532nm.

   The device is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos. It is for prescription use only.

7. Indications for Use
   The ND:YAG Laser is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.

8. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

ITEM	Proposed Device	Predicate Device K161926	Remark
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE
Where used	hospital	hospital	SE
Intended Use	The ND:YAG Laser is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.	The ND YAG Q-switch Laser Therapy Machine is indicated for the treatment of: Benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; Benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.	SE

Tab 2 Technical Comparison

ITEM	Proposed Device	Predicate Device K161926	Remark
Laser Medium	Nd:YAG	Nd:YAG	SAME
wavelength	1064 nm 532 nm	1064 nm 532 nm	SAME
Output energy	100-1000mJ for 1064nm 50-500mJ for 532nm	100-1000mJ for 1064nm 50-500mJ for 532nm	SAME
Max. Energy Density	31.8J/cm^2 15.9 J/cm^2	31.8J/cm^2 15.9 J/cm^2	SAME
Spot Size	2-10mm	2-10mm	SAME
Pulse Width	5ns-8ns	5ns-8ns	DIFFERENT
Frequency	1-10 Hz	1-10 Hz	SAME
Disinfection	The outer surface of the system may be wiped clean with a soft cotton cloth swabbed in 70% alcohol and a non-abrasive medical grade anti-bacterial is recommended. Be careful not to spill any liquids on the unit.	Disinfect the handpiece before and after every treatment by 75% medicinal alcohol	SIMILAR
Laser Class	Class 4	Class 4	SAME
Aiming Beam	Red (650nm) laser, ≤5mW	Red Laser, <6mW	SAME

Tab 3 Safety Comparison

Item	Proposed Device	Predicate Device K161925	Remark
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

9. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 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 compatibility- Requirements and tests.
- Software Validation & Verification Test
- Bench Testing to verify the performance

10. Clinical Testing

No clinical study is included in this submission.

11. Conclusion

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