November 27, 2019

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: K192519
Trade/Device Name: Multi-modality workstation, Model: AAD Dual Light
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: ONF
Dated: September 9, 2019
Received: September 13, 2019

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,

Purva Pandya
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)*
K192519

Device Name
Multi-modality workstation, Model: AAD Dual Light

Indications for Use *(Describe)*
The Multi-modality workstation (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

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 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: K192519

1. Date of Preparation: 11/27/2019

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Multi-modality workstation
Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Model(s): AAD Dual Light

Regulatory Information:
Classification Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology；
Classification: II;
Product Code: ONF;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Indication For Use Statement:
The Multi-modality workstation (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

Device Description:
The Multi-modality workstation is an intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 520nm-1200nm. Intense Pulsed Light (IPL) systems work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

IPL Systems are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores.

Based on this, the Multi-modality workstation (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in permanent hair removal, and reduction of benign pigmented lesions and benign vascular lesions.

5. Identification of Predicate Device(s)

510(k) Number: K161286
Predicate Device Name: IPL Therapy Machine
Manufacturer: Beijing ADSS Development Co., Ltd

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications to support that it is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device conforms to the following standards:

a) IEC60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
b) AAMI/ANSI/ES 60601-1:2005/A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
c) IEC60601-2-57:2011, Medical electrical equipment -- Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
d) IEC 62471 First edition 2006-07，Photobiological safety of lamps and lamp systems
e) ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
f) ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 9-1 General Comparison

ITEM	Proposed Device	Predicate Device IPL Therapy Machine VE2000 (K161286)	Remark
Product Code	ONF	ONF	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	II	II	SAME
Intended Use	The Multi-modality workstation (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.	The VE2000 device is indicated for use in surgical, aesthetic applications in permanent hair reduction, reduction of benign pigmented lesions and benign vascular lesions. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.	SAME

Table 9-2 Performance Comparison

ITEM	Proposed Device	Predicate Device IPL Therapy Machine VE2000 Systems(K161286)	Remark
Light source	Intense pulsed light	Intense pulsed light	SAME
Wavelength	520-650; 800~1200; 540-800; 640-1200;	480nm—1200nm 590nm—1200nm 640nm—1200nm	Analysis 1
Deliver system	Sapphire	Sapphire	SAME
Energy density	1-50J/cm²	1-50J/cm²	SAME
Pulse Width	1-25ms	1-25ms	SAME
Max. Power	3500VA	2200W	Analysis 5
Spot size	Small: 40 x 12 mm Large: 46 x 16mm Ex-Large: 60 x 20mm	12x30mm	Analysis 1

Table 9-3 Setting Comparison of Specified Indication for Use

ITEM	Proposed Device	Predicate Device IPL Therapy Machine VE2000 (K161286)	Remark
hair removal			
Wavelength Range (nm)	640-1200	640-1200	SAME
Energy Range (J/cm2)	5 to 40	10-44	SIMILAR
Pulse Width (ms)	1-25	3-14	Analysis 3
Spot Size (mm)	Small: 40 x 12 mm Large: 46 x 16mm Ex-Large: 60 x 20mm	12x30mm	Analysis 4
pigmented lesions			
Wavelength Range (nm)	540-800	480-1200	Analysis 1
Energy Range (J/cm2)	1-30	12-44	Analysis 2
Pulse Width (ms)	1-20	3-9	Analysis 3
Spot Size (mm)	40 x 12 mm	12x30mm	Analysis 4
vascular lesions			
Wavelength Range (nm)	520-650; 800-1200	590-1200	Analysis 1
Energy Range	5-30	10-42	Analysis 2

(J/cm2)			
Pulse Width (ms)	1-15	3-8	Analysis 3
Spot Size (mm)	40 x 12 mm	12x30mm	Analysis 4

Difference Analysis:

#1: Wavelength

The wavelength range of proposed devices is very closed to that of predicate devices. The slight difference is considered to have no negative effect on effectiveness and safety, and the bench tests conducted on the proposed device support substantial equivalence to the predicate device.

#2: Energy Range

The proposed device has an energy output range that is similar to the predicate device, and the slight differences do not result in negative safety and efficacy effects. The bench tests conducted on the proposed device support substantial equivalence to the predicate device.

#3: Pulse Width

The proposed device has a similar pulse width range as the predicate device. The slight difference in settings do not result in negative safety and effectiveness. The bench tests conducted on the proposed device support substantial equivalence to the predicate device.

#4: Spot Size

The proposed device has different spot size with the predicate device. However the differences in spot sizes are not considered to produce a negative effect on safety and safety. The bench tests conducted on the proposed device support substantial equivalence to the predicate device.

#5 Max Power

The maximum input power of the proposed device is different from the predicate device. However, the proposed device conforms to IEC 60601-1 and IEC 60601-1-2 regarding device safety and electromagnetic compatibility

Table 9-4 Safety Comparison

ITEM	Proposed Device	Predicate Device IPL Therapy Machine VE2000 (K161286)	Remark
Power supply	110V, 60Hz or 230V, 50Hz	110V 50Hz	Analysis 6
Electrical Safety	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The proposed devices were tested to demonstrated to comply with IEC 60601-1	SE
EMC	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	SE

Patient Contact Material	Handpiece	Handpiece	SE
Biocompatibility			
Cytotoxicity	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)	SE
Irritation	Applied sample did not induce irritation to skin. (ISO 10993-10)	Applied sample did not induce irritation to skin. (ISO 10993-10)	SE
Sensitization	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	SE

#6 Power Supply

The power supply of the proposed device is different from the predicate device. However, the proposed device conforms to IEC 60601-1 and IEC 60601-1-2 regarding device safety and electromagnetic compatibility.

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.