



August 16, 2019

Shanghai Apolo Medical Technology Co., Ltd.
% Claire Zhang
Manager
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705 , Building 1, West Guangzhong Road 555,
Jingan District, Shanghai, 200071 China

Re: K191349

Trade/Device Name: 980nm Diode Laser Therapy Device
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: May 17, 2019
Received: May 20, 2019

Dear Claire Zhang:

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,

Neil R. P. Ogden, M.S.
Acting Team Assistant Director
Light Based Devices Team
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

Section 2-Indication For Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K191349

Device Name

Diode Laser Therapy Device

Indications for Use (Describe)

HS-890A 980nm Diode Laser Therapy Device is intended for use in surgical application requiring the vaporization , incision, excision, ablation, cutting and hemostasis or coagulation of soft tissue. Such as vascular lesions and dental procedure.

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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Section 3-510(k) summary

I Submitter

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II Proposed Device

Trade Name of Device: 980nm Diode Laser Therapy Device
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: Class II
Product code: GEX
Review Panel: General & Plastic Surgery

III Predicate Devices

510(k) Number: K151890
Trade name: Medical Diode Laser Systems
Common name: Powered Laser Surgical Instrument
Classification: Class II
Product Code: GEX
Manufacturer: Wuhan Gigaa Optronics Technology Company., Ltd.

IV Device description

The Diode Laser Therapy Device is a desktop device which utilizes a semiconductor diode with invisible infrared radiation as a laser source (980nm). The laser power is delivered to the treatment via a delivery system.

The proposed device includes power supply system, delivery system, control system, cooling system and laser system.

V Indication for use

The Diode Laser Therapy Device is intended for use in surgical application requiring the vaporization, incision, excision, ablation, cutting and hemostasis or coagulation of soft tissue. Such as: vascular lesions and dental procedure.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K151890)
Product name	Diode Laser Therapy Device	Medical Diode Laser System
Product Code	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II
Model	HS-890A	VELAS II-30B
Indication for use	The Diode Laser Therapy Device is intended for use in surgical application requiring the vaporization, incision, excision, ablation, cutting and hemostasis or coagulation of soft tissue. Such as: vascular lesions and dental procedure.	The “VELAS II-30A/30B” are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including Vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology

		Endovascular coagulation, Oral Surgery and Dental Procedures, Lase assisted lipolysis.
Laser Type	GaA1As Diode Laser	GaA1As Diode Laser
Components	Laser system, Color touch screen, Fiber, Footswitch	Laser system, Color touch screen, Fiber, Footswitch.
Wavelength	980nm±10nm	VELAS II-30B: 980nm±10nm
Output power	1-30W	1-30W
Pulse width	5~400ms	10ms~2.5s
Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse
Light Delivery system	Fiber core diameter: 300µm, NA=0.22 With SMA905 connector	Fiber core diameter: 400µm, 600µm NA≥0.22 With SMA905 connector
Aiming beam	650nm, ≤2mW , adjustable	Diode laser of 635/532nm power max.<5mW, adjustable.
Laser class	4	4
Operation interface	Color LCD touch screen	Color LCD touch screen
Power supply	100-240VAC, 50/60Hz	100-240VAC, 50/60Hz,
Dimension	280mm[W]× 270mm[L]× 370mm[H]	400mm[W]×385mm[L]×200mm[H]
Weight	8kg	12.9kg
Safety classification	Class I	Class I
Software	Yes	Yes

VII Non-Clinical Testing

A battery of tests have been performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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

IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements

IEC 60601-2-22:2007(third edition) +A1:2012 for use in conjunction with IEC 60601-1:2005 (third edition) +A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

VIII Clinical Testing

It is not applicable.

IX Conclusion

Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.