October 13, 2022

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
Contact Address

Re: K221770
Trade/Device Name: Fiber Laser Treatment System
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: ONG
Dated: July 6, 2022
Received: July 13, 2022

Dear Felix Li:

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,

Jianting Wang
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)*
K221770

Device Name
Fiber Laser Treatment System

Indications for Use *(Describe)*
The Fiber Laser Treatment System is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

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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K221770

Section 3-510(k) summary

I Submitter

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II Proposed Device

Trade Name of Device:	Fiber Laser Treatment System
Common name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product code:	ONG
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K192350
Trade name:	Medical Non-ablative Fractional Laser Systems
Common name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Classification:	Class II
Product Code:	ONG
Manufacturer	Wingderm Electro-Optics Ltd.

IV Device description

The Fiber laser Treatment system (HS-230) is the desktop type. It consist of mainframe(touch-screen data input system, power supply control system and cooling system)，fiber treatment handpiece (laser output system) and footswitch.

The Fiber Laser Treatment System is a Erbium fiber laser, producing a pulsed beam of near-infrared light (1550nm) upon activation by a footswitch. The beam is then directed to treatment zone by mean of an optical fiber couple to a handpiece.

V Indication for use

The Fiber Laser Treatment System is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K130193)
Product name	Fiber Laser Treatment System	Medical Non-ablative Fractional Laser Systems
Product Code	ONG	ONG
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II
Model	HS-230	WFB-01
Indication for use	The Fiber Laser Treatment Systems is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.	The Medical Non-ablative Fractional Laser Systems (Model: WFB-01) is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.
Laser Type	Erbium glass	Erbium glass
Components	Laser system, Color touch screen, Fiber handpiece, Footswitch	Laser system, Color touch screen, Fiber, handpiece Footswitch.
Wavelength	1550nm	1550nm
Output power	15W	15W
Pulse energy	1-70mJ	Up to 70mJ
Pulse width	10ms	10ms
Beam delivery system	Fiber and handpiece	Fiber and handpiece
Laser beam diameter	110μm	110μm
Beam diameter variability	Fixed	Fixed
Dot Density	25~484 (18 level)	500

(Dot/cm^2)		
Laser emission control	Footswitch	Footswitch
Scanning area	Adjustable， Maximum treatment area：20mm*20mm	AccuTip: 10mm*10mm， EffiTip: 20mm*20mm GrowTip: 10mm*20mm
Laser class	Class 4	Class 4
Operation interface	Color LCD touch screen	Color LCD touch screen
Power supply	100-240VAC, 50/60Hz	100-240VAC, 50/60Hz,
Software	Yes	Yes
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
Performance	Comply with IEC 60601-2-22 and IEC 60825-1	Comply with IEC 60601-2-22 and IEC 60825-1
Material Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1

VII Non-Clinical Testing

A series of tests to verity 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-Part1-2: 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 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

The proposed device has the same/similar indication for use, has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.

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