July 2, 2025

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
Building 11, Lane 1566, Nanle Road, Songjiang District
Shanghai, Shanghai 201613
China

Re: K251031
Trade/Device Name: Fiber Laser Treatment Systems (HS-232, HS-233)
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: March 26, 2025
Received: April 3, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.07.02 13:59:56 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251031

Device Name
Fiber Laser Treatment Systems (HS-232, HS-233)

Indications for Use *(Describe)*
1550nm: The Fiber Laser Treatment Systems is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

1927nm: The Fiber Laser Treatment Systems is intended for use in dermatological procedures requiring the 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K251031

510(k) Summary

Prepared on: 2025-05-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shanghai Apolo Medical Technology Co., Ltd.
Applicant Address	Building 11, Lane 1566, Nanle Road, Songjiang District Shanghai Shanghai 201613 China
Applicant Contact Telephone	+86-2134622015
Applicant Contact	Mr. Felix Li
Applicant Contact Email	liqiang@apolo.com.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Fiber Laser Treatment Systems (HS-232,HS-233)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument With MicrobeamFractional Output
Regulation Number	878.4810
Product Code(s)	ONG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221770	Fiber Laser Treatment System	ONG
K130193	Fraxel® Dual 1550/1927 Laser System	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Fiber laser Treatment systems (HS-232) is the desktop type, and (HS-233) is the mobile 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 an Erbium(1550nm) and Thulium(1927nm) fiber laser, producing a pulsed beam upon activation by a footswitch. The system is equipped with a 650nm aiming beam with less than 2mW, the beam is then directed to treatment zone by mean of an optical fiber couple to a handpiece.
The 1550nm laser and 1927nm laser works independently and cannot work together, the output laser source can be selected according to different indication for use

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

1550nm: The Fiber Laser Treatment Systems is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

1927nm: The Fiber Laser Treatment Systems is intended for use in dermatological procedures requiring the coagulation of soft tissue.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The 1550nm indication of the proposed device is same as the predicate,the 1927nm indication of the proposed device is covered by the

predicate.

Technological Comparison 21 CFR 807.92(a)(6)

Discussion:
1550nm:
- Indication for use: the indication for use of the proposed device is the same as the predicated device.
- Technology: the proposed device utilizes the same technology as the predicates to achieve the intended use. The technical specifications including frequency, energy and pulse width are similar. Both devices meet the same standards of safety, EMC and performance requirements.
- Material: The handpiece tip that contacts the patient are identical to that of the Fiber Laser Treatment System (K221770) manufactured by Shanghai Apolo, including the material, color, size, etc., so the contact part of the handpieces of the both devices comply with ISO 10993-1.
1927nm:
Analysis 1: The indication for use of the proposed device is covered by the predicated devices.
Analysis 2: From the above comparison, the output power of proposed device is 15W, the output power of predicate device is not exactly same, but the output power of proposed device is similar with higher value of output power of the predicate device, the minor difference does not the affect the indication of proposed device. The pulse energy is largely same as the predicate device, only the lowest energy is different, the lower pulse energy does not arise new safety issues.
Analysis 3: The aiming beam and treatment area of the proposed device are similar with the predicate device's, the spot size and of the proposed device is within the range of the predicate device, so those minor difference does not affect the safety and effectiveness of device.
Analysis 4: The 1550nm and 1927nm laser using the same handpiece with treatment tip to output the laser power. The handpiece tip that contacts the patient are identical to that of the Fiber Laser Treatment System (K221770) manufactured by Shanghai Apolo, including the material, color, size, etc.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Testing:
A battery of tests was 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+A1:2012+ A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for the 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

Clinical Testing:
It is not applicable.

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