June 27, 2025

RiSu Medical Technology Co., Ltd.
Tianqiang Yu
Management Representative
Rm 201, Bldg 11, Western Cloud Valley(Phase III)
intercection of Kangding Road and Tongwen Road
Fengxi New City of Xixian New Area, Shaanxi 712000
China

Re: K251329
Trade/Device Name: Diode laser device (RF3120-BI)
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: April 30, 2025
Received: April 30, 2025

Dear Tianqiang Yu:

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: 2025.06.27 11:06:25 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251329

Device Name
Diode laser device (RF3120-BI)

Indications for Use *(Describe)*
The Diode laser device is intended for use in dermatology procedures requiring coagulation.The indications for use for the Trio-Wavelength Handpiece include: The Fast Hair Removal (FHR) Mode is intended for temporary hair reduction.The HR mode is intended for use in dermatology procedures requiring coagulation. The indications for use for the HR mode include: Benign vascular and vascular dependent lesions.
The 810nm wavelength handpiece is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and FHR Modes).

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) #: K251329

510(k) Summary

Prepared on: 2025-06-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	RiSu Medical Technology Co., Ltd.
Applicant Address	Rm 201, Bldg 11, Western Cloud Valley (Phase III), The intersection of Kangding Road and Tongwen Road, Fengxi New City of Xixian New Area Shaanxi 712000 China
Applicant Contact Telephone	+86-18910677558
Applicant Contact	Mr. Tianqiang Yu
Applicant Contact Email	information@believe-med.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Diode laser device (RF3120-BI)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222064	The Alma Soprano Titanium	GEX
K230580	Diode Laser System	GEX
K241951	Lasya-Trinity	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Diode Laser device includes two handles with different laser band characteristics. One handle contains a single-band 808nm semiconductor laser, and the other handle contains a three-band (755nm/808nm/1064nm) semiconductor laser. The semiconductor lasers of the two handles are powered by the laser power supply in the host to emit laser of corresponding wavelength.
Working principle of semiconductor laser
Semiconductor laser uses semiconductor materials of different doping types as laser working substance, uses natural cleavage surface to form resonant cavity for laser oscillation and amplification, and adds forward voltage to PN junction area of semiconductor laser to form particle number inversion of non-equilibrium carrier between conduction band and valence band of semiconductor substance. When a large number of electrons and holes in particle number inversion state are recombined, excess energy will be released, and these energies will be expressed in the form of photons, that is, laser is formed. Due to resonance amplification of cleavage surface resonant cavity, stimulated feedback is realized, so that laser can be directionally emitted and output from semiconductor laser.
The Diode laser device consists of a main unit, a handheld, a foot switch and a power cord.
Mode Description
1) Trio FHR Mode
The Diode Laser device Trio-Wavelength module with FHR mode is intended for temporary hair reduction.
In this mode, there is a set of parameter setting ranges. The specific parameter ranges are as follows: Frequency is 10 Hz and energy

fluence is 2-8J/cm2. The operator can adjust the parameters within this range according to the actual situation.
2) Trio HR Mode
The Diode Laser device Trio-Wavelength module with HR mode is intended for use in dermatology procedures requiring coagulation. The indications for use for the HR mode include: Benign vascular and vascular dependent lesions.
In this mode, there is a set of parameter setting ranges. The specific parameter ranges are as follows: Frequency is 1-10 Hz and energy fluence is 2-60J/cm2. The operator can adjust the parameters within this range according to the actual situation.
3) 810nm wavelength
The 810nm wavelength handpiece is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI)including tanned skin. (HR, and FHR Modes)
HR Mode: In this mode, there is a set of parameter setting ranges. The specific parameter ranges are as follows: Frequency is 1-10 Hz and energy fluence is 2-60J/cm2. The operator can adjust the parameters within this range according to the actual situation.
FHR Mode: In this mode, there is a set of parameter setting ranges. The specific parameter ranges are as follows: Frequency is 10 Hz and energy fluence is 2-8J/cm2. The operator can adjust the parameters within this range according to the actual situation.
The FHR Mode of the two handpiece (810nm& Trio-Wavelength) is the fast hair removal mode. This mode means a quick option for pulse frequency. In the FHR mode, the frequency is fixed at 10Hz and cannot be adjusted. The FHR mode of the 810nm handpiece is used for permanent reduction in hair regrowth defined as a long term, while the FHR mode of the Trio -wavelength handpiece is used for temporary hair reduction.
The HR mode of the two handpiece (810nm& Trio-Wavelength) is designed to differentiate from the FHR mode in terms of parameters. The HR mode covers all pulse frequency ranges (frequency: 1 - 10 Hz), and the pulse frequency can be adjusted. The HR mode of the 810 nm handpiece is used for permanent reduction in hair regrowth defined as a long term, while the FHR mode of the Trio -wavelength handpiece is used for benign vascular and vascular dependent lesions.
4) Operation Differences:
In terms of user operation, the software has two operation modes: HR mode and FHR mode. After startup, there will be a selection interface for these two modes. Users can click on different modes to enter different interfaces. In the HR mode interface, users can adjust the frequency and energy fluence through the up and down buttons. In the FHR mode interface, the frequency cannot be adjusted, and only the energy fluence can be adjusted through the up and down buttons. Other operations are the same for both modes.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Diode laser device is intended for use in dermatology procedures requiring coagulation. The indications for use for the Trio-Wavelength Handpiece include: The Fast Hair Removal (FHR) Mode is intended for temporary hair reduction. The HR mode is intended for use in dermatology procedures requiring coagulation. The indications for use for the HR mode include: Benign vascular and vascular dependent lesions.
The 810nm wavelength handpiece is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and FHR Modes).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed device has the same indications for use with the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device shares same laser classification, laser module power, laser wavelength, pulse width, pulse frequency, power input and cooling method, but has minor differences in spot size (trio-wavelength handpiece), energy fluence (HR and FHR modes of trio-wavelength handpiece), spot size (808 nm handpiece), pulse frequency (HR mode of 808 nm handpiece), and energy fluence (HR and FHR mode of 808 nm handpiece).
For the difference about spot size (trio-wavelength handpiece):
The spot sizes between the proposed device (12 x 20mm) and the predicted device(2 cm2 and 4 cm2) are very similar.
The difference on spot size would not impact the safety and effectiveness, because the final safety and effectiveness about clinical indications will depends on the amount of energy output per unit area, which would produce thermal effects to the patient's skin area irradiated to achieve claimed indication for use. Therefore, this difference will not affect the safety and effectiveness.

For the difference about energy fluence (HR mode of trio-wavelength handpiece):
The energy fluence of predicte device K222064 is 2-120J/cm2, while the propose device is 2-60J/cm2. It is lower than 120J/cm2, the safety of the product is no problem. However, the effectiveness cannot be determined, so we selected reference device K241951 with the same indication for use for energy fluence comparison. The energy fluence of the reference device is Max 60 J/cm2, which is similar with the energy fluence of the proposed device, and the pulse width and the pulse frequency are comparable to proposed device, so the energy irradiated on the patient's skin is similar with that of proposed device.
Thus the energy fluence of proposed device could achieve its indication for use without effectiveness concerns.

Therefore, this difference will not affect the safety and effectiveness.

For the difference about energy fluence (FHR mode of trio-wavelength handpiece):
For the difference on energy fluence between the predicate and proposed device, The energy fluence of predicate device K222064 is 2-20J/cm2, while the propose device is 2-8J/cm2. It is lower than 20J/cm2, the safety of the product is no problem. However, the effectiveness cannot be determined, so we selected reference device K230580 with the same indication for use for energy fluence comparison. The energy fluence of the reference device is 1-8J/cm2, which is similar to the energy fluence of the proposed device, and the pulse width and the pulse frequency are comparable to proposed device, so the energy irradiated on the patient's skin is similar to the proposed device.
Thus the energy fluence of proposed could achieve its indication for use without effectiveness concerns.
Therefore, this difference will not affect the safety and effectiveness.

For the difference about spot size (808 nm handpiece):
The spot sizes between the proposed device (12 x 12mm) and the predicted device(1 cm2 and 2 cm2) are very similar.
The difference on spot size would not impact the safety and effectiveness, because the final safety and effectiveness about clinical indications will depends on the amount of energy output per unit area, which would produce thermal effects to the patient's skin area irradiated to achieve claimed indication for use. Therefore, this difference will not affect the safety and effectiveness.

For the difference about pulse frequency (HR mode of 808 nm handpiece):
The HR mode pulse frequency of predicate device K222064 is 0.5-3Hz, while the propose device is 1-10Hz.
We selected reference device K230580 with the same indication for use for pulse frequency comparison, the pulse frequency of the propose device is within the frequency range of K230580, so the effectiveness of the product is not affected. Therefore, this difference will not affect the safety and effectiveness.

For the difference about energy fluence (HR mode of 808 nm handpiece):
For the difference on energy fluence between the predicate and proposed device, The fluence of predicte device K222064 is 2-120J/cm2, while the propose device is 2-60J/cm2. It is lower than 120J/cm2, the safety of the product is no problem. However, the effectiveness cannot be determined, so we selected reference device K230580 with the same indication for use for fluence comparison. The energy fluence of the reference device is 1-50J/cm2, which is similar to the fluence of the proposed device, and pulse width and pulse frequency are comparable to proposed device, so the energy irradiated on the patient's skin is similar to the proposed device; thus the energy fluence of proposed could achieve its indication for use without effectiveness concerns. Therefore, this difference will not affect the safety and effectiveness.

For the difference about energy fluence (FHR mode of 808 nm handpiece):
The energy fluence of the proposed device is within the range of that of the predicate device, which can justify that the difference in the parameter of energy fluence will not raise new safety issues of the proposed device. And the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test and IEC 60825-1 test, the safety and performance of the product can be ensured.
Therefore, this difference will not affect the safety and effectiveness.

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

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
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
ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Test

The clinical study is not applicable.

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performance as well as the legally marketed predicate device, the Alma Soprano Titanium cleared under K222064.