August 9, 2022

Bio-Med USA Inc
Young Chi
CEO
27 New England Dr
Ramsey, New Jersey 07446

Re: K221789
Trade/Device Name: IRIS Pi Q switched Nd YAG laser
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: June 16, 2022
Received: June 21, 2022

Dear Young Chi:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221789

Device Name

IRIS Pi Q switched Nd YAG laser

Indications for Use *(Describe)*

IRIS Pi Q switched Nd YAG laser system is indicated for the Incision, Excision, Ablation Vaporization of soft tissues for general dermatology, dermatologic and general surgery procedures for Coagulation and Hemostasis

532nm wavelength
- Tattoo removal light ink (red, tan, purple, orange, sky blue)
- Removal of benign epidermal pigmented lesions, Minor benign vascular lesions, Talangietasias
- Treatment of Lentigines, Cafe-Au-Lait, Sebrorrheic Keratoses, Becker's Nevi, Freckles.
- Treatment of Post inflammatory Hyperpigmentation (PIH)

1064nm wavelength
- Tattoo removal dark ink (black, blue, green)
- Removal of Nevus of Ota,
- Removal or lightening of unwanted hair,
- Treatment of Common Nevi, Melasma
- Skin resurfacing procedures for treatment of Acne Scars, Wrinkle

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (K) Summary

As required by CFR 807.92(c)

1. Manufacturer.

Prepared July 25, 2022

BlueCore company Co., Ltd. (Reg3014144061)
Acehigh 21, 48 Centum-Jungang ro 12
Haeundae Gu, Busan, Rep of Korea
T: 82 51 747 4318, F: 82 51 747 4319

2. Submitter

Bio-Med USA Inc.
Young Chi, C E O.
27 New England Drive, Ramsey, NJ 07446. U.S.A.
t: 1 973 278 5222 f: 1 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name	:	IRIS Pi Q switched Nd:YAG laser
Classification name :	:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Common name	:	Powered, Laser Surgical instrument
Regulation	:	878.4810 Class II
Product Code	:	GEX
Type of submission	:	Traditional

4. Legally marketed Predicate Device

K171648	BM.IRIS	Nd:YAG	Bluecore Company Co Ltd

5. Device Description

The IRIS Pi Q-Switched Nd:YAG laser system produces a two pulsed beam, 1064 nm Infrared and 532nm long pulse laser, and using two non-fractional handpieces (Zoom handpiece and 7mm collimated handpiece) is able to control various treatment fluence.

laser tube : placed in the mixed crystals of copper pipe to the heater and produces a laser beam,
Resonator : amplifies the beam, through the Xe-gas contained lamp
lamp : Xe-gas contains high pressure lamp to increase specific laser beam

This converted light energy creates the Nd:YAG crystal and exhaust from the crystal is amplified into a specific wave length. Laser energy produced is delivered to the tissue by means of an articulated arm and a specially designed adjustable spot size Hand Piece.

The Physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam, and is able to activate laser emission using Foot Switch. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit.

This system also consist of

Optic main Bench assembly, Articulated Arm Hand pieces, LCD control panel, Cooling system, Foot Pedal Switch

6. Indication for use

IRIS Pi Q-switched Nd : YAG Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength

Tattoo removal light ink (red, tan, purple, orange, sky blue,)
Removal of Benign Epidermal Pigmented Lesions, Minor Benign Vascular Lesions, Talangiectasias
Treatment of Lentigines, Cafe-Au-Lait, Sebrorrheic Keratoses, Becker's Nevi, Freckles
Treatment of Post inflammatory Hyperpigmentation (PIH)

1064nm Wavelength:

Tattoo removal: dark ink (black, blue, green)
Removal of Nevus of Ota
Removal or lightening of unwanted hair with or without adjuvant preparation
Treatment of Common Nevi, Melasma,
Skin resurfacing procedures for the treatment of acne scars, wrinkle

7 Comparison to Predicate Device

Device & Predicate Device(s):	K221789	K171648	Comment
General Device Characteristics			
Laser Type	Nd YAG	Nd YAG	Same
Wavelength	1064/532 nm	1064/532 nm	Same
Operating Mode	Q-switched	Q-switched	Same
Mode Names	1064, 532, SLP, BLUE T	1064, 532, SLP, BLUE Toning	Same
Maximum Pulse Energy (mJ)	1600 @ 1064 nm (Q) 500 @ 532 nm (Q) 2000 @ 1064 nm (SLP) 1500 @ 1064 nm (BLUE T)	1200 @ 1064 nm (Q) 400 @ 532 nm (Q) 1500 @ 1064 nm (SLP) 1000 @ 1064 nm (Blue Toning, PTP)	Different
Spot Size (mm)	2-10 @ 1064 nm 2-10 @ 532 nm	2-10 @ 1064 nm 1.5-8 @ 532 nm	Comparable

		K221789	
Pulse Duration (ns)	5-10 @1064 nm (Q) 5-10 @ 532 nm (Q) 5-10 @ 1064 nm (SLP) 5-10 @ 1064 nm (BLUE T)	5-10 @1064 nm (Q) 5-10 @ 532 nm (Q) 5-10 @ 1064 nm (SLP, Non Q) 5-10 @ 1064 nm (Blue Toning, PTP)	Same
Repetition Rate (Hz) @ spot size	1-10 @ 2-10mm @1064nm (Q) 1-10 @ 2-10mm @ 532nm (Q) 1-10 @ 2-10mm @1064nm (SLP) 1-10 @ 8-10mm @1064 nm (BLUE T) 1-15 @ 2-7 mm @ 1064 nm (BLUE T)	10-20 @ 2-10mm @1064nm (Q) 10-20 @ 2-10mm @ 532nm (Q) 10-20@ 1-10mm @ 1064 nm (SLP, Non Q) 10-18 @ 8-10mm, @ 1064nm (Blue Toning, PTP) 10-20 @ 2-7mm @ 1064nm (Blue Toning, PTP)	Different
Aiming Beam	<3 mW @ 655 nm	<3 mW @ 655 nm	Same
Cooling system	Water cooling	Water cooling	Same
Dimensions	270 x 700 x 750 mm	295 x 740 x 1680 mm	Comparable
Weight	90 kg	70 kg	Comparable

The majority of the technical parameters of subject device are comparable to and/or fall within the range of the corresponding technical parameters of the predicate device, Since the maximum repetition rate for the subject device is lower than that of the predicate device, the energy delivered by the subject device is lower Than or comparable to the predicate device. Thus, difference are not expected to significantly alter the safety and effectiveness of the subject device compared to the predicate device

8.Performance test

Clinical data is not required in this submission, but manufactured in accordance with below both mandatory and voluntary standards, performance test data attached.

AAMI/ANSI ES60601-1:2005® 2012 And A1:2012
part 1 : General requirement for basic safety and essential performance.
IEC60601-1-2: 2014 Electro Magnetic Compatibility test
IEC60601-2-22 Part 2, Particular requirements for safety of diagnostic and Therapeutic laser
IEC60825-1 :2nd ED, Equipment classification and requirement.
IEC60601-2 Part 6 General requirements for safety * Collateral Standard: Usability

Software Verification and Validation test was conducted and documentation provided as recommended by FDA guidance and IEC62304, Device software verification and validation result were found acceptable for software release

Biocompatibility

This device are meant non-contacted mode.
Hand piece tips has guard which are made by S.S.304 same as predicate device.

9. Conclusion.

IRIS Pi Q-Switched Nd: YAG laser system, in this submission is the same or similar to the predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance, although, there are minor different in Pulse Energy and Repetition rate, every performed safety test report show it as safe and effective as predicate device and, it does not raise any additional issues for safety and effectiveness.