October 6, 2021

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

Re: K212082
Trade/Device Name: Picore
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: September 1, 2021
Received: September 8, 2021

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); 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,

Purva Pandya
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)*
K212082

Device Name
PICORE

Indications for Use *(Describe)*
PICORE 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

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) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K212082

1. Date of Preparation
   10/05/2021

2. Applicant

Name:	Bio-Med USA Inc.
Contact Name:	Young Chi, C.E.O.
Address:	27 New England Drive, Ramsey, NJ 07446. U.S.A.
Telephone:	1 973 278 5222
Fax:	1 201 934 6030
Email:	biomedusa@msn.com

3. Manufacturer

Name:	BlueCore Co., Ltd.
Address:	Acehigh 21, 48 Centum-Jungang ro 12, Haeundae Gu, Busan, Rep of Korea.
Telephone:	82 51 747 4318
Fax:	82 51 747 4319
Registration #	3014144061

4. Identification of the Proposed Device

Trade/Device Name:	PICORE
Common Name:	Nd:YAG Q-switched Surgical Laser
Classification Name:	Powered Laser Surgical Instrument
Classification:	II
Product Code:	GEX
Regulation Number:	21 CFR 878.4810
Review Panel:	General& Plastic Surgery

5. Identification of Predicate Device

510(k) Number:	K171648
Trade/Device Name:	BM.IRIS
Manufacturer:	BlueCore Co. Ltd.

6. Device Description
   The subject device PICORE is a picosecond Nd:YAG laser instrument that uses Nd:YAG as a medium to emit a laser beam of 1064nm and 532nm wavelength. It has four non-fractional handpieces (Zoom handpiece, 7mm collimated handpiece, 3-5 mm handpiece, 6-8 mm handpiece). A physician can optimize the treatment effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam. Laser emission can be controlled by using a Foot Switch. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit.

7. Indications for Use – The indications for use statement of the subject device PICORE is given below. The indications for use of the PICORE is comparable to the indications for use of the predicate device BM.IRIS (K171648). Both devices are for prescription use only.

   PICORE 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

8. Substantially Equivalent (SE) Comparison

Tab 1 Technical Comparison

Technical Specification	**Subject Device (K212082)**	**Predicate Device (K171648)**	**Comment**
Laser Type	Nd:YAG	Nd:YAG	same
Wavelength (nm)	1064/532	1064/532	same
Operating Mode	Q-switched, Pulsed	Q-switched, Pulsed	same
Mode Names	1064, 532, Blue Fx, Blue T	1064, 532, SLP, Blue Toning	
Spot size (mm)	2-10 @ 1064nm 2-10 @ 532nm	2-10 @ 1064nm 1.5-8 @ 532nm	comparable
Maximum Pulse Energy (mJ)	50-800 @ 1064nm (Q) 5-300 @ 532nm (Q) 50-800 @ Blue Fx 50-800 @ Blue T	1200 @1064nm (Q) 400 @ 532nm (Q) 1500 @ 1064 nm (SLP, Non Q) 1000 @ 1064nm (Blue Toning, PTP)	different & subset
Maximum Pulse Power (GW)	800 mJ/450ps = 1.8 GW	1200 mJ/5ns = 0.24 GW	different
Pulse Duration	450 ps @ 1064nm 380 ps @ 532nm 450 ps @ Blue Fx 450 ps @ Blue T	5-10ns @1064nm (Q) 5-10ns @ 532nm (Q) 5-10ns @ 1064 nm (SLP, Non Q) 5-10ns @ 1064nm (Blue Toning, PTP)	different
Repetition Rate (Hz) @ spot size (mm)	1-10	10-20 @ 2-10mm @1064nm (Q) 10-20 @ 2-10mm @ 532nm (Q) 10-20@ 1-10mm @ 1064 nm (SLP, Non Q) 10-20 @ 2-7mm @ 1064nm 10-18 @ 8-10mm, @ 1064nm (Blue Toning, PTP)	different & subset
Aiming Beam	<3 mW @ 655 nm	<3 mW @ 655 nm	same
LCD Display	10.4'' touch screen	10.4'' touch screen	same
Cooling	Closed circuit water to air	Closed circuit water to air	same
Power Consumption	3kVA	3kVA	same
Dimensions	290mmX794mmX934mm	295mmX740mmX1680mm	comparable
Weight	60 kg	70 kg	comparable

Majority of the technical parameters of the subject device are comparable to and/or fall within the range of the corresponding technical parameters of the primary predicate device. The difference in technological parameters is not expected to significantly alter the safety and effectiveness of the subject device compared to the predicate device.

9. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. Biocompatibility testing was not performed since the handpieces of the subject device do not touch patients and are exactly the same as in the predicate. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 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 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- Software Validation & Verification Test
- Bench Testing to verify the performance

10. Clinical Testing

No clinical study is included in this submission.

11. Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.