DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 8, 2017

Bluecore Co.,Ltd.
% Young Chi
C.E.O
Bio-Med USA Inc
111 Ellison Street
Paterson, New Jersey 07446

Re: k171648
Trade/Device Name: Bm.iris
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: May 28, 2017
Received: June 5, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171648

Device Name
IRIS

Indications for Use *(Describe)*

IRIS 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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510 (K) Summary

As required by CFR 807.92(c)

1. Manufacturer. Submitter Prepared Aug 20, 2017

BlueCore Co., Ltd.
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Haeundae Gu, Busan, Rep of Korea
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2. Contact person

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Young Chi, President.
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	:	BM.IRIS
Classification name :	:	Powered, Laser surgical instrument
Common name	:	Nd:YAG Q-switched Surgical Laser
Regulation	:	878.4810 Class II
Classification Panel	:	General and Plastic Surgery.
Product Code	:	GEX
Type of submission	:	Traditional

4. Legally marketed Predicate Device

K113588	Spectra	Nd:YAG	Lutronic Corp

BM.IRIS Q-Switched Nd:YAG laser system produce same two wave length (1064nm, 532nm), and same characteristics such as Design, Construction, Energy rate, Pulse Duration, Cooling system and intended use as already cleared predicate device K113588 by Lutronic,

5. Device Description

The IRIS Q-Switched Nd:YAG laser system produces a two pulsed beam, 1064 nm Infrared and 532nm long pulse laser, and using different Handpiece 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 multi spot 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

This device has optional 180mm Dye Hand Pieces to able to switch to 585nm or 650nm from 532nm.

6. 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.

IEC60601-1 part 1 : General requirement for basic safety and essential performance.
IEC60601-1-2: 2007 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.

7. Indication for use

IRIS 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**. Biocompatibility**

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

9**. Conclusion.**

BM.IRIS Q-Switched Nd: YAG laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance.
And every Safety test report show it as safe and effective as predicate device and it does not raise any additional issues for safety and effectiveness**.**