October 10, 2024

Bluecore Company Co., Ltd.
Sang Mi Oh
Official Correspondent
#1203, 48, Centurm Jungang-Ro, Haeundae-Gu
Busan, KR 48059
Korea, South

Re: K241951
Trade/Device Name: Lasya-Trinity
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 13, 2024
Received: July 03, 2024

Dear Sang Mi Oh:

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: 2024.10.10 23:46:19 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241951

Device Name
Lasya-Trinity

Indications for Use *(Describe)*
The Lasya-Trinity diode laser system is intended for use in dermatology procedures requiring coagulation with the following indications:
The trinity applicator is indicated for benign vascular and vascular dependent lesions.
The 808 applicator is indicated for permanent reduction in hair regrowth.
Use on all skin types (Fitzpatric I-VI), including tanned skin.

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.

510(k) summary (510(k) #: K241951)

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

I. Submitter Information [21 CFR 807.92(a) (1)]

Applicant/Manufacturer Name	BLUECORE COMPANY Co., Ltd.
Applicant Address	#1203, 48, Centum Jungang-Ro, Haeundae-Gu Busan KR 48059 Korea, South
Contact Person	Sangmi Oh Regulatory Affairs Manager Tel.: +82 070 4870 5146 Fax: +82 051 747 4319 E-mail: osm7832@bluecorecompany.com
Date Prepared	October 8, 2024

II. Name of device [21 CFR 807.92 (a) (2)]

Device Trade Name	Lasya-Trinity
Common Name	Lasya-Trinity Diode Laser System
Classification Name	Power Laser Surgical Instrument
Regulation Number	21 CFR 878.4810
Product Code	GEX

III. Predicate Devices [21 CFR 807.92(a) (3)]

Predicate #	K230371
Predicate Trade Name	Soprano Titanium
Product Code	GEX

IV. Device Description [21 CFR 807.92(a) (4)]

The Subject device, Trinity-Lasya is a diode laser instrument that use diode as a medium to emit a laser beam of 755 & 808 & 1064nm wavelength.

There are two handpiece, the user can choose from. Moreover, a specific software controls the device functions and allows the user selections through the touchscreen display.

the system is intended to be used in user facilities such as hospitals, physicians' offices and medical spas, and its major components are the main console unit, foot switch, and individual modules.

The device is re-usable and non-sterile; instructions for cleaning its components between uses are provided in the labeling.

Lasya-Trinity Laser System consists of:

- System console (contains the system software, power supply, and various other electronic and mechanical parts)
- Operator control panel with touch-screen technology (GUI)
- Trinity applicator(handpiece) with 1064 nm, 808nm and 755 nm wavelengths applied simultaneously
- 808 applicator(handpiece) with 808nm wavelength
- Footswitch and etc.

V. Intended use of device and Indications for Use [21 CFR 807.92(a) (5)]

The Lasya-Trinity diode laser system is intended for use in dermatology procedures requiring coagulation.

The indications for use for the Lasya-Trinity include:
Trinity applicator intended use and indications for use: benign vascular and vascular dependent lesions.
808 applicator intended use and indications for use: permanent reduction in hair regrowth.
Use on all skin types (Fitzpatric I-VI), including tanned skin.

VI. Summary of technological characteristics of the device compared to the predicate [21 CFR 807.92(a)(6)]

The subject Lasya-Trinity system shares with its predicate Soprano Titanium system (K230371) the same underlying technology and presents similar technological characteristics. Both systems use laser energy, delivered to the skin surface, via applicators.

The subject Lasya-Trinity is substantially equivalent to the cleared Soprano Titanium with respect to the hardware and software elements of the system, the principles of operation and the product design.

	Predicate Device	Subject Device
Product Name	Soprano Titanium (Trio 2 cm² applicator)	Lasya-Trinity (Trinity applicator)
510(k) Number	K230371	K241951
Manufacturer	Alma Lasers Inc.	BLUECORE COMPANY Co., Ltd.
Laser Medium	Diode	Diode
Wavelength	755&810&1064 nm	755&808&1064 nm
Handpiece	Trio 2 cm²	Trinity applicator
Operational mode	HR	HR
Fluence	1~120 [J/cm^2]	Max.60 [J/cm^2]
Frequency (Repetition Rate)	up to 10 [Hz]	1 – 10 [Hz]
Pulse Width (Pulse Duration)	Up to 200 [ms]	5 ~ 200 [ms]
Spot Size	2 [cm²]	2 [cm²]
Indications for Use	Benign vascular and vascular dependent lesions	Benign vascular and vascular dependent lesions

	Predicate Device	Subject Device
Product Name	Soprano Titanium (808 2 cm² applicator)	Lasya-Trinity (808 applicator)
510(k) Number	K230371	K241951
Manufacturer	Alma Lasers Inc.	BLUECORE COMPANY Co., Ltd.
Laser Medium	Diode	Diode
Wavelength	810 nm	808nm
Handpiece	810 applicator	808 applicator
Operational mode	HR	HR
Fluence	Max. 60 [J/cm^2]	Max.60 [J/cm^2]
Frequency (Repetition Rate)	0.5 – 3 [Hz]	1 – 3 [Hz]
Pulse Width (Pulse Duration)	3.3 ~ 200 [ms]	5 ~ 200 [ms]
Spot Size	20 * 10 [mm²]	2 [cm²]
Indications for use	Permanent reduction in hair regrowth	Permanent reduction in hair regrowth

VII. Performance Testing [21 CFR 807.92(b)(1)]

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for safety and essential performance
IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance
IEC 60601-2-22 – Medical Electrical Equipment – Part 2-22 – Particular Requirements for basic

safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1, Safety of laser products - Part 1: Equipment classification, and requirements

In addition, software verification and validation testing was performed to the requirements of IEC 62304 and biocompatibility conformance to FDA standards was established.

VIII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject, reference, and primary predicate devices, no animal or clinical studies were deemed needed to support this submission.

IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

The Lasya-Trinity is as safe and effective as the predicate Soprano Titanium. The proposed Lasya-Trinity has the same intended use and indications, similar technological characteristics, and same principle of operation as its predicate device.

Thus, the Lasya-Trinity is substantially equivalent to its predicate.