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

August 9, 2017

Ilooda Co. LTD
% Ms. Kathy Maynor
Emvera Technologies, LLC
641 10th St
Cedartown, Georgia 30125

Re: K172096
Trade/Device Name: Ilooda Fraxis CO2 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, ONG
Dated: July 10, 2017
Received: July 11, 2017

Dear Ms. Maynor:

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 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 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)*
K172096

Device Name
Ilooda Fraxis CO2 Laser

Indications for Use *(Describe)*

- C02 LASER Part:
Fractional mode is indicated only for ablative skin resurfacing.
Non-fractional mode is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.

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.

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Section 8 – 510(k) Summary or 510(k) Statement

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

Submitter:	Ilooda 120, Jangan-Ro 458 Beon-Gil Jangan-Gu Suwon-Si Gyeonggido, KOREA, REPUBLIC OF 16200
Contact Person:	Kathy Maynor Consultant 352-586-3113 (cell) Kmaynor77@gmail.com
Summary Preparation Date:	August 9, 2017

II. Names [21 CFR 807.92 (a) (2)]

Device Names:	The Ilooda Fraxis CO2 Laser
Primary Classification Names:	Surgical Powered Light Instrument,
Regulation No.:	21 CFR 878.4810
Device Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	GEX, ONG
Device Class:	II

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

K #	Predicate Device
K160312	Fraxis Duo

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

The Ilooda Fraxis CO2 Laser is comprised of the following major components:

1. The main console unit
2. Delivery handpieces (2)
3. Footswitch.
4. Accessories

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

V. Indications for Use [21 CFR 807.92(a) (5)]

- CO2 LASER Part:
Fractional mode is indicated only for ablative skin resurfacing.
Non-fractional mode is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues
including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery),
otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.

VI. Summary of Technical Characteristics Compared to Predicate [21 CFR 807.92(a)(6)]

Table 1: Salient Characteristics of the Ilooda Fraxis CO2 Laser and the Predicate Device

Characteristic	**K172096** **Ilooda Fraxis CO2 Laser**	**K160312** **Fraxis Duo**
Product Code & Regulation No.	**GEX, ONG** **21 CFR 878.4810**	**GEX** **21 CFR 878.4810**
Laser Type	CO2	CO2
Laser wavelength	10.6µm	10.6µm
Output power	30W	30W
Pulse Duration	20-5,000µs	20-5,000µs
Fractional Pulse energy	Max 150mJ	Max 150mJ
Repetition rate	1,000Hz	1,000Hz
Scan area	20x20mm	20 x 20mm
Spot size	100-200µm Non-fractional: Max 1.3mm	100-200µm Non-fractional: Max 1.3mm
Number of microbeams per surface area (fractional)	Max 289 spot/cm2	Max 289 spot/cm2
Energy per microbeam (fractional)	150mJ	150mJ
Total power per surfaced area (fractional)	Max 30W	Max 30W
Treatment Time	10-15 min	10-15 min
Pulse rate (non-fractional)	1Hz – 1,000Hz	1Hz – 1,000Hz

Pulse width (non-fractional)	20µs – 5000µs	20µs – 5000µs
Operational mode	Fractional mode, normal mode (CW, Pulse, Single Pulse)	Fractional mode, surgical mode (CW, pulsed, single pulse)
Aiming beam	Diode laser(Red), Max 4mW	Diode laser(Red), Max 4mW
Cooling	Air cooling	Air cooling
User Interface	LCD touch screen	LCD touch screen
Optical guide	Articulated arm	Articulated arm
Electrical Requirements	100-240VAC, 50-60 Hz, 6.3 A,	100-240VAC 50-60 Hz
Indications for Use	- CO2 LASER Part: Fractional mode is indicated only for ablative skin resurfacing. Non-fractional mode is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.	- CO2 LASER Part: Fractional mode is indicated only for ablative skin resurfacing. Non-fractional mode is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery. - HF electrosurgical Part : The FRAXIS DUO is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

VII. Differences Between the Fraxis and Fraxis Duo

The Fraxis does not have the RF micro-needling handpiece or a handpiece named GynoLase, so they are not included in the equivalence chart above. These handpieces are included in the Fraxis Duo, the predicate device.

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

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for safety
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 60825-1Safety of laser products-Part 1: Equipment Classification, requirements and user's guide

In addition, software verification and validation testing was performed and biocompatibility was established.

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

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

X. Conclusion

The Ilooda Fraxis CO2 laser was found to be substantially equivalent to the predicate devices.

The Ilooda Fraxis CO2 laser shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.