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

October 28, 2016

Ilooda Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K160312
Trade/Device Name: Fraxis Duo
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, GEI, OUH
Dated: January 27, 2016
Received: February 5, 2016

Dear Dave Kim:

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 yours,

Jennifer R. Stevenson -A

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)*
K160312

Device Name
FRAXIS DUO
Instrument, surgical, powered, laser
Micro-needle Fractional RF

Indications for Use *(Describe)*

- 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

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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"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."

Traditional 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: October 20, 2016

I. SUBMITTER

Submitter's Name :	ILOODA CO LTD.
Submitter's HQ Address:	120, Jangan-ro 458 Beon-gil, Jangan-Gu, Suwon-Si Gyeonggido, KOREA, 16200
Submitter's Telephone:	+82 (031) 210 1622
Contact person:	Yun-Jung HA (yjha@ilooda.com) / RD Manager
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DEVICE	
Trade/proprietary name:	FRAXIS DUO
Common or Usual Name:	Instrument, surgical, powered, laser Micro-needle Fractional RF
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4810 (Product Code: GEX) 21 CFR 878.4400 (Product Code: GEI, OUH)
Regulatory Class:	Class II
Prescription Use.	

PREDICATE DEVICE

Primary Device Manufacturer:	Quanta System SpA
Device Name:	YOULASER C02
510(k) Number:	K123573
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810 (Product Code: GEX)
Regulatory Class:	Class II

This predicate has not been subject to a design-related recall.

Reference Device Manufacturer:	EndyMed Medical Ltd
Device Name:	Intensif Applicator (Ilooda Secret)
510(k) Number:	K130501
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: OUH, GEI)
Regulatory Class:	Class II

This predicate has not been subject to a design-related recall.

II. DEVICE DESCRIPTION

FRAXIS DUO is a combination of two separate systems: CO2 laser and HF electrosurgical system.
The Laser and High Frequency(=Radio frequency) can not be used simultaneously.
FRAXIS DUO's CO2 laser includes the system main body, differenthandpieces(Fractional type, Non-fractional type), footswitch and an LCD Touch screen control panel.
FRAXIS DUO's CO2 laser utilize a CO2 RF tube to generate a laser beam with a wavelength of 10,600nm and use different handpiece(Fractional type, Non-fractional type) for different indications for use. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different handpiece.
The laser are supplied with different handpieces depending upon the device configuration.

FRAXIS DUO's High Frequency(=Radio Frequency) includes the system main body, a Bipolar handpiece equipped with disposable micro-needle electrodes, footswitch and an LCD touch screen control panel.
The HF energy is delivered using disposable micro-needle electrodes.

III. 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.

- ***HF electrosurgical part***

  The FRAXIS DUO is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	FRAXIS DUO	**EndyMed Pro / Intensif Applicator (Ilooda Secret) (K130501)**	**YOULASER CO2 (k123573)**
Manufacturer	Ilooda	EndyMed Medical Ltd	Quanta System SpA
Intended 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* YOULASER CO2 laser when used in traditional, non fractionated 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), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery. YOULASER CO2laser when used in fractionated mode (dot scanner) is indicated only for ablative skin resurfacing."

		FRAXIS DUO	EndyMed Pro / Intensif Applicator (Ilooda Secret) (K130501)	YOULASER CO2 (k123573)
		-HF electrosurgical Part : The FRAXIS DUO is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis	The Intensif Applicator is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.	
Electrosurgical RF applicator		Intensif Applicator (Ilooda Secret) (K130501)	Intensif Applicator (Ilooda Secret) (K130501)	
Output energy type		CO2 / High frequency	High Frequency	CO2
Delivery system		***Laser Part*** Articulated Arm with Scanner, Normal(Smart surgi) Handpiece	-	Articulated arm + Normal or Scanner handpiece
		High frequency Part Bipolar Handpiece	Bipolar Handpiece	-
Operation mode		***Laser Part*** Fractional mode_ Scanner handpiece Normal mode (CW, Pulse, Single Pulse,Ultra)_ Normal handpiece	-	Fractional mode Surgical mode (CW, Pulse)
		-HF electrosurgical Part : Manual mode	Intensif mode	-
User interface		Color Touch Panel	Color Touch Screen	Color Touch Screen
Electrical Requirements		100-240VAC, 50/60Hz, 5-3A	100-230 VAC, 50-60Hz 1-3A,	115 V ac; 50/60 Hz; 1000 VA or 230 V ac; 50/60 Hz; 1000 VA
Dimensions (mm)		Main unit : 410(W)x601(D)x1071(H) Arm : Max 1,400(H)mm	Main Unit: 190 (W) x 300 (D) x 1150 (H)	Main unit : 480 (W) x 550(D) x 1200 (H) Arm : Not known
Weight (Without arm)		45kg	33 kg	55 Kg
Spec. _Laser	wavelength	10,600nm	-	
	Medium of transmission	CO2 Laser	-	CO2 Laser
	Aiming beam	Diode laser(Red), Max 4mW, 655nm	-	Red Laser Diode, 3mW
	power	Max 30W	-	Max 30W
	Cooling	Air cooling	-	Air cooling
	Scanning pattern		-	Area, Shape, Spot density

		FRAXIS DUO	EndyMed Pro / Intensif Applicator (Ilooda Secret) (K130501)	YOULASER CO2 (k123573)
	(Fractional)			
	Pulse energy (Fractional)	Max 150mJ	-	Up to 3J
	Pulse duration (Fractional)	20 ㎲ ~ 5,000 ㎲	-	50 µs – 20.000 µs
	Distance (Fractional)	1x1 ~ 20x20 mm	-	18x18mm
	Spot size	Fractional :100 ~ 120 ㎛ Non-fractional : Max 1.3mm	-	Fractional :200 ㎛ Non-fractional : 200µm, 400µm, 1000 µm
	Pulse repetition (Fractional)	1,000Hz		Up to 1kHz
	Number of microbeams per surface area (Fractional)	Max 289 spot/cm2		100, 200 & 500 spot/cm2
	Energy per Microbeam (Fractional)	150mJ		Fluence per microbeam 9.9 ÷84.8 J/cm2 (from Quanta USA website)
	Total power per surface area (Fractional)	Max.30W		Max 30W
	Treatment distance	0.1mm - 2.0mm		Not known
	Treatment time	10-15min		Not known
	Pulse rate (Non-fractional)	1Hz - 1,000Hz	-	2,000Hz
	Pulse width (Non-fractional)	Ultra : 20 ㎲ ~ 5000 ㎲	-	Surgical : up to 100 ms
Spec. _HF	High frequency	2MHz ± 10%	1MHz ± 10%	
	Max power	Max 25W at 500Ω	Max 25W at 500Ω	
	Total power delivered per treatment	Max.25W	Max.25W	
	Power of per electrode pin	Max.25W	Max.25W	
	Power density	41W/㎠	41W/㎠	
	Current density	0.3A/㎠	0.3A/㎠	
	RF duration	50 ms ~ 950 ms	50 ms ~ 950 ms	
	Treatment time	10~15min (recommended)	10~15min (recommended)	
	Needle insert depth	0.5 ~ 3.5mm (0.1 step)	0.5 ~ 3.5mm (0.1 step)	
	Intensity	0 ~ 10 LEVEL (2/5/10 STEP)	0 ~ 10 LEVEL (2/5/10 STEP)	

		FRAXIS DUO	EndyMed Pro / Intensif Applicator (Ilooda Secret) (K130501)	YOULASER CO2 (k123573)
	Repetition	0.2 / 0.5 / 1 / 2 sec / Single	0.2 / 0.5 / 1 / 2 sec / Single	
	Connected handpiece	Bipolar handpiece	Intensif handpiece (Bipolar type)	
	Connected electrodes	MTR-AC-25 MTR-AC-64	Intensif 25 pin electrode	

V. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility testing:

FRAXIS DUO is equipped with the electrosurgical RF applicator, Intensif Applicator (Ilooda Secret), K130501. The patient contact components and materials are tested and validated according to ISO10993-1;2009.

Non Clinical testing:

IEC 60601-1 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance. The requirements of specified standards were fulfilled.

IEC 60601-1-2 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance (collateral standards: electromagnetic compatibility.

EN 60825-1: Safety of laser products-Part 1: Equipment classification and requirements

EN 60601-2-22: Medical electrical equipment- part 2: particular requirements for the safety of diagnostic and therapeutic laser equipment.

The requirements of specified standards were fulfilled.

Animal testing :

Laser part

In vivo animal testing using micropig models was also conducted to obtain histological data of values for depth and zone of ablation and thermal damage immediately post treatment; 7 days post treatment; and 14 days post treatment.

The animal study results show that fractional mode and non-fractional mode of FRAXIS

DUO is safe for use and effective.

HF electrosurgical part

In vivo animal testing using micropig models was also conducted to obtain histological data of values for depth and zone of ablation and thermal damage immediately post treatment; 7 days post treatment; and 14 days post treatment.
The treatment was performed at the intensity(power) low, mid, high and depth of micro-needling 1.0mm, 2.0mm, 3.0mm.
Additional preclinical performance test was performed to investigate animal study comparing the 2MHz and 1MHz high-frequency characteristics effect on tissue.
FRAXIS DUO and predicate device were performed in the same condition(Depth : 2.0mm, Power : 30W).
Histologic evaluation was done by H&E for immediately after procedure.
Histologically, both FRAXIS DUO and predicate device created conical diamond shaped tissue coagulation in the dermis and show similar coagulated pertten.
Histologically, both FRAXIS DUO and predicate device created tissue coagulation in the dermis and show similar coagulated pattern.

VI. CONCLUSIONS

There are no significant differences between the FRAXIS DUO and the predicate device.
The proposed device does not raise any questions regarding safety and effectiveness.
FRAXIS DUO has the same indications for use as the predicate devices.
It shares the same technological characteristics as the predicate devices.
Some minor differences do not raise any new questions regarding safety or effectiveness of FRAXIS DUO.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Ilooda Co, Ltd. concludes that FRAXIS DUO is safe and effective and substantially equivalent in comparison with Intensif Applicator (Ilooda Secret) (K130501) and YOULASER CO2 (K123573), the predicate devices
as described herein.