December 1, 2017

Ilooda Co., Ltd.
% Kathy Maynor
Regulatory Consultant
Ronyam Enterprises LLC
26 Rebecca Ct
Homosassa, Florida 34446

Re: K173038
Trade/Device Name: CuRAS Nd:YAG 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
Dated: September 25, 2017
Received: September 28, 2017

Dear Kathy 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K173038

Device Name
CuRAS Nd:YAG Laser

Indications for Use *(Describe)*

The CuRAS Nd;YAG laser system in 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, skyblue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
- Tattoo removal: dark ink (black, blue and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and 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.

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

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

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Summary Preparation Date: September 25, 2017

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

Trade or Proprietary Name	Ilooda CuRAS Nd:YAG Laser		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Laser Powered Surgical Instruments (& Accessories) Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 878.4810, Laser surgical instrument for use in general and plastic surgery and dermatology
	Surgical Powered Lasers and Delivery Devices/Hand piece Accessories		

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

K #	Predicate Device
K122922	E-Beam Nd;YAG Laser system

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

The CuRAS Nd;YAG laser system is comprised of the following major components:

1. The main console unit
2. Delivery handpieces

3. Footswitch.
4. Accessories

The system is intended to be used in user facilities such as hospitals, physicians' offices and medical spas.

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

The CuRAS Nd;YAG laser system in 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, skyblue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
- Tattoo removal: dark ink (black, blue and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkle

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

Table 1: Technical Comparison for the Q-switched Laser

Parameter	**CuRAS Nd;YAG laser system (K17XXX)**	**E-Beam Nd;YAG laser system (K122922)**
Product Code & Regulation No.	**GEX 21 CFR 878.4810**	**GEX 21 CFR 878.4810**
Laser Medium	Nd:YAG	Nd:YAG
Laser wavelength	1064nm/532nm	1064nm/532nm (Option : 585nm, 650nm)
Output energy	Max 1.6J @1064 nm Max 0.4J @532 nm	Max 1.2J @1064 nm Max 0.4J @532 nm
Pulse width	5-20ns	5-10ns
Repetition Rate	1-15Hz	Single, 1,2,5,10 Hz

Spot size	2mm-10mm	2-8 mm @ 1064 nm 6.9mm@532nm
Aiming beam	Diode 635nm 5mW	Diode 655nm(Red) 1mW
Operational mode	Q-switched	Q-switched
User Interface	LCD touch screen	LCD touch screen
Optical guide	Articulated arm	Articulated arm
Electrical Requirements	220-230VAC, 50-60 Hz,	220VAC 50-60 Hz
Indications for Use	The CuRAS Nd;YAG laser system in 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, skyblue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of Lentigines - Treatment of Cafe-Au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper-Pigmentation - Treatment of Becker's Nevi, Freckles and Nevi Spilus 1064nm Wavelength: - Tattoo removal: dark ink (black, blue and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation. - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkle	The E-Beam Nd;YAG laser system in 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, skyblue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of Lentigines - Treatment of Cafe-Au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper-Pigmentation - Treatment of Becker's Nevi, Freckles and Nevi Spilus 1064nm Wavelength: - Tattoo removal: dark ink (black, blue and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation. - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkle

Table 2: Technical Comparison for the Pulsed Laser

Parameter	**CuRAS Nd;YAG laser system (K17XXX)**	**E-Beam Nd;YAG laser system (K122922)**
Product Code & Regulation No.	**GEX** **21 CFR 878.4810**	**GEX** **21 CFR 878.4810**
Laser Medium	Nd:YAG	Nd:YAG
Operation mode	Pulsed	Long-pulsed

Energy per pulse	Max 1500mJ	1500mJ
Pulse duration	300 μs	300 μs
Spot size	2mm-10nn	2-8mm Collimated 6mm
Repetition rate	1-15Hz	Single 1,2,5,10Hz
Indications for Use	The CuRAS Nd;YAG laser system in indicated for : the incision,excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.	The E-Beam Nd;YAG laser system in indicated for : the incision,excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

VII. 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.

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. Conclusion

The CuRAS Nd;YAG laser system was found to be substantially equivalent to the predicate devices.

The CuRAS Nd;YAG laser system shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.