September 3, 2021

Daeju Meditech Engineering Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K211637
Trade/Device Name: Aroma Grand
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: July 30, 2021
Received: August 5, 2021

Dear April Lee:

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. 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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211637

Device Name
AROMA GRAND

Indications for Use *(Describe)*
The AROMA GRAND is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

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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510(k) Summary

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Device Information

- Trade Name: AROMA GRAND
- Common Name: Powered laser surgical instrument
- Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Product Code: GEX
- Panel: General & Plastic Surgery
- Regulation Number: 21 CFR §878.4810
- Device Class: Class II
- Date prepared: 08/19/2021

Predicate Device

Primary Predicate
K151232, VIKINI DIODE LASER SYSTEM by ILOODA Company, Ltd.

Indications for use

The AROMA GRAND is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

Device Description

The subject device, AROMA GRAND is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).
It utilizes a semiconductor diode as a laser source (808nm). The laser power is delivered to the treatment area via a laser hand-piece. The emission laser is activated by a footswitch.

Summary of Technological Characteristics

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	Remark
	AROMA GRAND	VIKINI DIODE LASER SYSTEM	
K number	K211637	K151232	
Product Code	GEX	GEX	Same
Regulation	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use	The AROMA GRAND is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regimen.	The VIKINI DIODE LASER SYSTEM is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regimen.	Same
Configuration	Main Unit, Hand-piece	Main Unit, Hand-piece	Same
Principle of Operation	Diode Laser	Diode Laser	Same
Laser Type	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Same
Laser Wavelength	808[㎚]	808[㎚]	Same
Spot Size	2.1[㎠] / 14*15[㎜]	1.32[㎠] / 12*11[㎜]	Analysis 1
Fluence	100[J/㎠]	120[J/㎠]	Analysis 2
Max. Output	100W/㎠	284W/㎠	Analysis 3

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	Remark
Frequency	1-10[Hz]	1-10[Hz]	Same
Power	600W	600W	Same
Purse duration	10-350[ms]	5-625[ms]	Analysis 4
Cooling system	Water cooling	Water cooling	Same
Optical Guide	Sapphire Crystal	Sapphire Crystal	Same
Power Supply	100-240V, 50/60 Hz	100-240V, 50/60 Hz	Same
Dimensions (L*W*H)	480*640*1,230[mm]	380*400*840 [mm]	Analysis 5
Weight	67[kg]	43[kg]	
Electrical Safety	Comply with IEC 60601-1 IEC 60601-2-22 IEC 60825-1	Comply with IEC 60601-1 IEC 60601-2-22 IEC 60825-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Analysis 1 – Spot size
The spot size of the proposed device is larger than the spot size of the predicate device. Fluency (energy density) is a key factor in laser therapy. The fluency of the proposed device is not much different from the fluency of the predicate device. Therefore, the difference on spot size is considered would not raise any issues in safety and effectiveness.

Analysis 2-Fluence
The fluence for the proposed device is different from predicate device. However, this difference is very slight and performance testing has been conducted on the proposed device and the test result can comply with related standards requirement. Therefore, this difference does not raise issues of safety or effectiveness.

Analysis 3-Max. Output
The Max. Output for the proposed device is different from predicate device. The value is calculated as Power*Pulse duration/Spot Size. Power is the same, but differences occur due to Pulse durations and Spot Size. First of all, check the analysis 1 and analysis 4. Therefore, this difference does not raise issues of safety or effectiveness.

Analysis 4-Pulse duration
The Pulse duration is most important parameter how long time the energy will deliver to the patient`s skin, it may affect the safety (too long action time) may burn patient`s skin. The Pulse duration of proposed device is 10-350ms, it`s less than the Pulse duration of predicate device. That`s means the proposed device could be consider as safety.

Analysis 5-Dimension and weight
The dimension and weight for the proposed device is different from predicate device. However, the dimension and weight difference are just in physical specification and this difference will not raise any issues in safety and effectiveness.

Non-clinical Testing Summary
The non-clinical testing results demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.

Biocompatibility Testing
The biocompatibility evaluation for the subject device was conducted in accordance with the guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing including cytotoxicity, Sensitization and Irritation are conducted according to the ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Electrical Safety and electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on Diode Laser Hair Removal Machine. The device complies with the following standards

- AAMI/ANSI/ES 60601-1:2005(R) 2012 and A1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.

Particular Performance Testing
Performance testing was conducted on the device according to the following standard:

- IEC 60601-2-22:2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Software Verification and Validation Testing
The software for this device was considered as a "Moderate" level of concern. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Accuracy Testing
The accuracy test was conducted to verify that the energy output and spot size of the proposed laser system do not deviate the tolerance of the setting value of energy output or the fixed value of spot size. The non-clinical testing results demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.

Clinical Testing
Not applicable.

Conclusion
Based on the comparison and analysis above, the proposed devices are determined to be as safe, as effective, and performs as well as the predicate device.