Laseroptek Co., Ltd.
% Paweena U-Thainual
CEO
MDR Solutions Co., Ltd.
1435 Kanchanapisek Rd., Bang Khae Nuea
Bangkok, 10160 Th

Re: K191501
Trade/Device Name: PALLAS 308/311 Solid-State UV Laser System
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: December 12, 2019
Received: December 13, 2019

Dear Paweena U-Thainual:

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); 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,

Jessica Mavadia-Shukla
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191501

Device Name
PALLAS 308/311 Solid-State UV Laser System

Indications for Use *(Describe)*
The indication for use are UVB phototherapy of psoriasis, vitiligo, atopic dermatitis, and leukoderma of affected 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

5. 510(k) Summary K191501

1. General Information

Applicant/Submitter:	Laseroptek Co., Ltd.
Address:	#116, #117, #203, #204 Hyundai I Valley, 31 Galmachi-ro, 244beon-gil, Jungwon-gu Seongnam-*Si*, Gyeonggido, 13212 Rep. of Korea (South Korea)
Contact Person:	Paweena U-Thainual MDR Solutions Co., Ltd.
Address:	1435 Kanchanapisek Rd., Bang Khae Nuea, Bang Khae, Bangkok 10160, THAILAND Tel: +66-2-804-2101 Fax: +66-2-804-2100 Email: paweena@mdrsolutions.co.th
Preparation Date:	June 5th, 2019

2. Device Name and Code

Device Trade Name:	PALLAS 308/311 Solid-State UV Laser System
Common Name:	UV Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	GEX
Regulation Number:	878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery (ODE)

3. Technical Characteristics in Comparison to Predicate Devices

Predicate Device: K172639 - PALLAS 308/311 Solid-State UV Laser System, Laseroptek Co., Ltd.

Technical characteristic changes in comparison of modified device to unmodified device were specified in following table.

	Unmodified/Predicate Device	**Modified/Proposed Device**
510(K) Number	K172639	N/A
Manufacturer	Laseroptek Co. Ltd.	Laseroptek Co. Ltd.

Device Name	PALLAS Solid-State UV Laser System	PALLAS Solid-State UV Laser System
Clearance Date:	November 3, 2017	N/A
Classification / Regulation	Class 2 / 878.4810	Class 2 / 878.4810
Product Code	GEX	GEX
Intended Use	UVB phototherapy of psoriasis, vitiligo, atopic dermatitis, and leukoderma of affected skin.	UVB phototherapy of psoriasis, vitiligo, atopic dermatitis, and leukoderma of affected skin.
Mode of Operation	Monochromatic UVB Phototherapy	Monochromatic UVB Phototherapy
Wavelength	308 nm or 311 nm	308 nm or 311 nm
Output:		
Beam Profile	Flat-top, Non-Gaussian	Flat-top, Non-Gaussian
Maximum Pulse Duration	15 to 20 ns	15 to 20 ns
Output Energy per Pulse	Up to 4.2 mJ	5.0 mJ
Fluence per pulse (mJ/cm^2)	3.5 - 4.4 mJ/cm^2	3.47 mJ/cm^2
Physical Characteristics:		
Activation	Via foot-switch	Via foot-switch
Cooling system	Radiator	Chiller
Electrical Requirements	AC 230 V, 50/60 Hz	AC 230 V, 50/60 Hz
Maximum Power	20W	20W

4. Device Description

Laseroptek Co. Ltd.'s PALLAS 308/311 Solid-State UV laser system is a self-contained ultraviolet laser light source and optical energy delivery system that provides targeted energy to the treatment site while avoiding exposure to non-affected tissue. The light source is contained within the protective console. The complete system also includes a hand piece connected to the console via an articulating arm. Timing and dosing parameters and the user interface are controlled through a display on the console. The delivery system allows UV-B light to pass through the hand piece to selectively treat skin legions without exposure to the unwanted skin.

5. Indications / Intended Use

UVB phototherapy of psoriasis, vitiligo, atopic dermatitis, and leukoderma of affected skin.

6. Performance Data

Non-clinical tests: Measurement of wavelength, average output power, and energy fluence (in units of mW/cm2) of treatment were performed. Testing conducted on the PALLAS 308/311 Solid-State UV Laser System shows that it refers to the relevant mandatory performance standards for laser products 21 CFR 1040.10 and 1040.11. Other performance, such as electromagnetic compliance, etc, were tested using following consensus standards:

- PALLAS 308/311 Solid-State UV Laser System is tested and evaluated according to IEC 60601-1:2005 (Third Edition) + CORR.1:2006+ CORR. 2:2007 + A1:2012 or IEC 60601-1:2012 reprint. All the results presented here demonstrated general requirements for basic safety and essential performance.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to IEC 60601-1-2: 2007 (Third Edition). All the results presented here demonstrated the requirements and tests for electromagnetic disturbances.
- PALLAS 308/311 Solid-State UV Laser System is tested according to IEC 60601-1-6:2010, AMD1:2013
- PALLAS 308/311 Solid-State UV Laser System is tested and evaluated according to FDA-recognized consensus standard IEC 60601-2-22: 2007 (Third Edition) + A1:2012. All the results presented here demonstrated the particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- Safety of laser products is evaluated according to IEC 60825-1: 2014 (Third Edition). All the results presented here demonstrated the equipment classification and requirements.
- Risk management was recorded according to ISO 14971: 2012. All the results presented here demonstrated the application of risk management to medical devices.
- Usability was documented according to ISO 14971: 2012 and IEC 62366. All the results presented here demonstrated the application of risk management to medical devices.
- Software Validation was reported according to IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION

The portion of the device that touches patient body is made of aluminum alloy 6061, which have been used for other medical devices without any biocompatibility risk.

7. Substantial Equivalence

The subject device has the same device characteristics as the predicate (unmodified) device. They have the same intended use and material. The differences are in hand-piece tip shape, output energy, and cooling system. However, the performance test shown that there is no technical characteristic difference in the modified device. The change in output energy does not raise any concerns regarding the device performance and safety as shown in **Section 6. Performance Data.** Therefore, PALLAS 308/311 Solid-State UV Laser System is substantially equivalence to the legally marketed unmodified/predicate device.

8. Conclusions

On the basis of the information provided in this Summary, Laseroptek Co., Ltd. Believes that PALLAS 308/311 Solid-State UV Laser System is substantially equivalent to legally marketed unmodified/predicate device.