January 26, 2023

Laseroptek Co., Ltd.
% Wonmi Lee
Manager
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, Seoul 06210
Korea, South

Re: K223588
Trade/Device Name: PALLAS Premium
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: November 30, 2022
Received: December 1, 2022

Dear Wonmi 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); 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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223588

Device Name
PALLAS Premium

Indications for Use *(Describe)*
PALLAS Premium is Solid-State Ultraviolet laser system for treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma.

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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6. 510(k) Summary

6.1 General Information

Applicant/Submitter:	Laseroptek Co., Ltd.
Address:	#114, #116, #117, #203, #204 Hyundai I Valley ,31, Galmachi-Ro, 244beon-gil, Jungwon-Gu, Seongnam-Si, Gyeonggi-do, 13212, Rep. of Korea (South Korea)
Contact Person:	Wonmi Lee, BT Solutions, Inc.
Address:	Unit 904, Eonju-ro 86gil 5, Gangnam-gu, Seoul 06210, Korea. Tel: +82-2-538-9140 Email: wmlee@btsolutions.co.kr
Preparation Date:	January 26, 2023

6.2 Device Name and Code

Device Trade Name:	PALLAS Premium
Common Name:	Solid-State UV Laser (Nd:YAG laser crystal)
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

6.3 Technical Characteristics in Comparison to Predicate Devices

The PALLAS Premium, is the same or similar with the following legally marketed predicate devices:

	Predicate Device 1	Proposed Device	Same or Similar
510(K) Number	K191501	Not Available	
Manufacturer	Laseroptek Co., Ltd.	Laseroptek Co. Ltd.	
Device Name	PALLAS 308/311 Solid-State UV Laser System	PALLAS Premium	
Product Code	GEX	GEX	YES
Classification / Regulation	Class II/ 21 CFR 878.4810	Class II/ 21 CFR 878.4810	YES

Laser type	Solid-State UV Laser (Nd:YAG laser crystal)	Solid-State UV Laser (Nd:YAG laser crystal)	YES
UV Spectrum	UVB	UVB	YES
Wavelength	308 nm or 311 nm	308 nm or 311 nm	YES
Pulse Duration (Max.)	15 to 20 ns	20 ns	YES
Pulse Energy (Max.)	Up to 5.0 mJ	Up to 5.0 mJ	YES
Fluence (Max.)	3.47 mJ/cm^2	3.47 mJ/cm^2	YES
Repetition rate	100 Hz	300 Hz	YES
Spot size	12 x 12 mm	12 x 12 mm 15 x 15 mm 18 x 18 mm	YES
Intended Use / Indications for Use	psoriasis vitiligo atopic dermatitis leucoderma	psoriasis vitiligo atopic dermatitis leucoderma	YES
Other Characteristics:			N/A
Beam Delivery System	Articulated arm with handpiece	Articulated arm with handpiece	YES
Interface	User interface control display	User interface control display	YES

Table 1. Comparison of the predicate device 1(K191501) and PALLAS Premium

	Predicate Device 2	**Proposed Device**	**Same or Similar**
510(K) Number	K193478	Not Available	
Manufacturer	Strata Skin Sciences, Inc.	Laseroptek Co. Ltd.	
Device Name	XTRAC Momentum Excimer Laser System, Model AL10000	PALLAS Premium	
Product Code	GEX	GEX	YES
Classification / Regulation	Class II/ 21 CFR 878.4810	Class II/ 21 CFR 878.4810	YES
Laser type	XeCl Excimer laser	Solid-State UV Laser (Nd:YAG laser crystal)	N/A*
UV Spectrum	UVB	UVB	YES
Wavelength	308 nm	308 nm or 311 nm	YES
Pulse Duration (Max.)	30 ns	20 ns	YES
Pulse Energy (Max.)	Up to 15 mJ	Up to 5.0 mJ	YES

Fluence (Max.)	3.8 mJ/cm^2	3.47 mJ/cm^2	YES
Repetition Rate (Max.)	400 Hz	300 Hz	YES
Spot size	20 x 20 mm	12 x 12 mm 15 x 15 mm 18 x 18 mm	YES
Intended Use / Indications for Use	psoriasis vitiligo atopic dermatitis leucoderma	psoriasis vitiligo atopic dermatitis leucoderma	YES
Other Characteristics:			N/A
Beam Delivery System	Liquid fiber-optic (LLG) with user-directed hand piece	Articulated arm with handpiece	YES
Interface	User interface control display	User interface control display	YES

Table 2. Comparison of the predicate device 2(K193478) and PALLAS Premium

6.4 Device Description

This device consists of a power supply unit, a cooling system, a controller, and a laser resonator, and is controlled by a microprocessor. When electric energy pumping is applied to the flash lamp, the laser is emitted through a device laser module that oscillates a laser with a wavelength of 311nm, and the laser is radiated through the end of the optical fiber, which is a laser carrier.

6.5 Indications / Intended Use

PALLAS Premium is Solid-State Ultraviolet laser system for treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma.

6.6 Performance Data

Non-clinical tests: Such as safety of laser product, electromagnetic compatibility and electrical safety, etc, were tested using following consensus standards:

- Basic safety and essential performance of the PALLAS Premium is tested and evaluated according to the FDA-recognized consensus standard, AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2.
- Safety of laser product is evaluated in accordance with IEC 60825-1.
- Basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment is evaluated in accordance with IEC 60601-2-22:2019.
- Risk management was recorded by referring to ISO 14971.

- Usability was documented by referring to IEC 60601-1-6.
- 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." The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator.

6.7 Biocompatibility testing

The biocompatibility evaluation for PALLAS Premium was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on Sep. 4, 2020 and International Standard ISO 10993-5:2009 and ISO 10993-10:2010.

Biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

PALLAS Premium is considered skin contacting for a duration of less than 24 hours. The contact is for the support of the device when in treatment, not for the treatment itself. All the materials used that contact patient skin are Aluminum alloy 6061.

6.8 Conclusions

The proposed device uses similar or identical technology as the predicate devices and has same intended uses. Based upon the predicted overall performance characteristics for PALLAS 308/311 Solid-State UV Laser System, Laseroptek Co., Ltd., and XTRAC Momentum Excimer Laser System, Model AL10000, Strata Skin Sciences, Inc., Laseroptek Co., Ltd. believes that no significant differences in usage of its underlying technological principles between PALLAS Premium and the predicate devices.

On the basis of the information provided in this Summary, Laseroptek Co. Ltd. Believes that PALLAS Premium is the same or similar with legally commercialized predicate devices for the purposes of this 510(k) submission.