December 8, 2021

Laseroptek Co., Ltd.
% Do Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, Seoul 06210
Korea, South

Re: K212573
Trade/Device Name: PicoLO 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: August 13, 2021
Received: August 16, 2021

Dear Do 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. 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,

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)*
K212573

Device Name
PicoLO Premium

Indications for Use *(Describe)*
PicoLO Premium is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

<Tattoo removal mode>
1064nm
The 1064nm wavelength of the PicoLO Premium is indicated for tattoo removal for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple
532nm
The 532nm wavelength of the PicoLO Premium is indicated for tattoo removal for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

<PH mode>
The PicoLO Premium is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.
The DIA FX 1064 handpiece (1064nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.
PicoLO Premium is also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.

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

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) Tel) +82.31.8023.5150 Fax) +82.31.8023.5151
Contact Person:	Do-Hyun Kim, BT Solutions, Inc.
Address:	904, Eonju-ro 86-gil 5, Gangnam-gu, Seoul, 06210, Republic of Korea Tel) +82.2.538.9140 Email) ceo@btsolutions.co.kr
Preparation Date:	November 4, 2021

2. Device Name and Code

Device Trade Name:	PicoLO Premium
Common Name:	Nd:YAG Laser System
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. Predicate Device

PicoLO Premium is substantially equivalent to the following devices

Table 5.1 Predicate device

Applicant	Device Name	510(k) Number
Laseroptek Co., Ltd.	PicoLO Nd:YAG Picosecond Laser System	K203491

4. Device Description

PicoLO Premium is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions. A key feature of the device is its ability to produce multiple laser wavelengths (1064 nm and 532 nm). The PicoLO Premium consists of a set of Q-switched Nd:YAG lasers, controlled by an embedded processor, to be used in dermatology. The laser system uses focusing optics to deliver a pattern of thermal energy to the epidermis and dermis. This system consists of main body, color touch screen, articulated arm, hand piece and foot switch.

5. Indications / Intended Use

PicoLO Premium is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

<Tattoo removal mode>
1064nm
The 1064nm wavelength of the PicoLO Premium is indicated for tattoo removal for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.

532nm
The 532nm wavelength of the PicoLO Premium is indicated for tattoo removal for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

<PH mode>
The PicoLO Premium is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.
The DIA FX 1064 handpiece (1064nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.
PicoLO Premium is also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.

6. Technical Characteristics in Comparison

6.1. Technical Characteristics in Comparison to Predicate Device

PicoLO Premium is substantially equivalent to the following legally marketed predicate device.

Table 5.2 Comparison table between Predicate device and Proposed device

	Proposed Device	**Proposed Device**
510(K) Number	K203491	
Product Code	GEX	GEX
Classification / Regulation	Class II/878.4810	Class II/878.4810
Manufacturer	Laseroptek Co.,Ltd.	Laseroptek Co.,Ltd.

Device Name	PicoLO Nd:YAG Picosecond Laser System	PicoLO Premium
Clearance Date	April 7, 2021	N/A
Intended Use / Indications for Use:	PicoLO laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. <Tattoo Mode> <u>1064nm</u> The 1064nm wavelength of the PicoLO laser system is indicated for tattoo removal for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. <u>532nm</u> The 532nm wavelength of the PicoLO laser system is indicated for tattoo removal for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. <PH Mode> The PicoLO laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The 1064 handpiece (1064nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V. The PicoLO laser system is also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.	PicoLO Premium is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. <Tattoo removal mode> 1064nm The 1064nm wavelength of the PicoLO Premium is indicated for tattoo removal for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. 532nm The 532nm wavelength of the PicoLO Premium is indicated for tattoo removal for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. <PH mode> The PicoLO Premium is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The DIA FX 1064 handpiece (1064nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V. PicoLO Premium is also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.
Wavelength	1064/532 nm (Accuracy ±20%)	1064/532 nm (Accuracy ±20%)

Pulse Duration (Pulse Width)	450ps (1064nm), (Accuracy ±20%) 380ps (532nm), (Accuracy ±20%)	450ps (1064nm), (Accuracy ±20%) 380ps (532nm), (Accuracy ±20%)
Pulse Energy (max)	Tattoo Mode 500mJ (1064nm), (Accuracy ±20%) 350mJ (532nm), (Accuracy ±20%) PH Mode* 400mJ (1064nm), (Accuracy ±20%) 200mJ (532nm), (Accuracy ±20%)	Tattoo Mode 500mJ (1064nm), (Accuracy ±20%) 350mJ (532nm), (Accuracy ±20%) PH Mode* 400mJ (1064nm), (Accuracy ±20%) 200mJ (532nm), (Accuracy ±20%)
Peak Power (Gigawatts)	1.1	1.1
Aiming Beam	Laser diode, 635nm/ <5mW	Laser diode, 635nm/ <5mW
Repetition Rate (Hz)	Single, M3, M5, 1~10Hz (Accuracy: ± 20%)	Single, M3, M5, 1~10Hz (Accuracy: ± 20%)
Spot size (mm)	1064 (10 mm) 532 (7 mm) Collimator (20 mm) Zoom (2~7 mm)	DIA FX 1064 (10mm) DIA FX 1064 S (5mm) DIA FX 532 (7mm) S20 (20mm) Collimator (10mm) Zoom (2~7 mm)
Laser Type	Q-switched Nd:YAG Laser	Q-switched Nd:YAG Laser
Activation	Via foot-switch	Via foot-switch
Display	TFT LCD Touch screen	TFT LCD Touch screen
Cooling System	Internal water to air heat exchanger	Internal water to air heat exchanger
Electrical Power	220-230VAC, 50/60Hz	220-230VAC, 50/60Hz
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece
System Dimensions(mm)	350(W) x 1080(L) x 970(H)	350(W) x 1080(L) x 970(H)
System Weight (kg)	110 kg	110 kg

PH mode* is intended for 3 newly added indications, as below;

1) benign pigmented lesions removal for Fitzpatrick Skin Types I-IV,
2) the treatment of acne scars in Fitzpatrick Skin Types II-V, and
3) the treatment of wrinkles in Fitzpatrick Skin Types I-IV.

7. Performance Data

Non-clinical tests: Testing conducted on the PicoLO Premium 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 standards:

- PicoLO Premium is tested and evaluated according to AAMI/ANSI ES60601-1:2005 and A1:2012. All the results presented in the submission demonstrate general requirements for basic safety and essential performance.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2: 2014. All the results presented here demonstrated the requirements and tests for electromagnetic disturbances.
- PicoLO Premium is tested and evaluated according to FDA-recognized consensus standard IEC 60601-1-6:2010/AMD1:2013. All the results presented here demonstrated the General requirements for safety - Collateral Standard: Usability.
- PicoLO Premium 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 IEC 60825-1: 2014. All the results presented here demonstrated the equipment classification and requirements.
- Risk management was recorded according to the FDA-recognized consensus standard ISO 14971: 2012. All the results presented here demonstrated the application of risk management to medical devices.
- Usability was documented according to the FDA-recognized consensus standard IEC 62366: 2008. All the results presented here demonstrated the application of usability engineering to medical devices.
- Biocompatibility was tested and evaluated according to FDA-recognized consensus standard ISO 10993-5: 2009 and ISO 10993-10: 2010.

8. Substantial Equivalence

The PicoLO Premium, subject of this submission, is modifications of the PicoLO Nd:YAG Picosecond Laser System cleared under K203491.

The modifications are:
(1) changing the names of three handpieces, and
(2) adding new two handpieces.

These modifications do not affect technological principles between the modified device and the predicate device.

Based upon the predicted overall performance characteristics for the PicoLO Premium, Laseroptek Co. Ltd. believes that no significant differences exist in usage of its underlying technological principles between PicoLO Premium and the predicate device.

9. Conclusions

The technological characteristics of the subject device PicoLO Premium are comparable to the predicate device for comparable indications for use. Thus, subject device PicoLO Premium is concluded to be substantially equivalent to the predicate.