January 4, 2019

Laseroptek Co., Ltd.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K183392
Trade/Device Name: PicoLO Nd:YAG Picosecond 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 6, 2018
Received: December 7, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K183392

Device Name
PicoLO Nd:YAG Picosecond Laser System

Indications for Use *(Describe)*

PicoLO laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.
1064nm
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.
532nm
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.

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: | #116, #117, #203, #204 Hyundai I Valley 31<br>Galmachi-*Ro*, 244beon-gil, Jungwon-*Gu*<br>Seongnam-*Si*, Gyeonggido, 13212<br>Rep. of Korea (South Korea)<br>Tel) +82.31.8023.5150<br>Fax) +82.31.8023.5151 |
| Contact Person: | Do-Hyun Kim, BT Solutions, Inc. |
| Address: | 904, Eonju-ro 86-gil 5,<br>Gangnam-gu, Seoul, 06210, Republic of Korea<br>Tel) +82.2.538.9140<br>Email) smanager@btsolutions.co.kr |
| Preparation Date: | January-3-2019 |

## 2. Device Name and Code

| | |
|---|---|
| Device Trade Name: | PicoLO Nd:YAG Picosecond Laser System |
| Common Name: | Nd:YAG 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. Predicate Device

PicoLO Nd:YAG Picosecond Laser System is substantially equivalent to the following devices

Table 5.1 Predicate device

| Applicant | Device Name | 510(k) Number |
|---|---|---|
| Syneron Candela Corporation | PicoWay Laser System | K170597 |

## 4. Device Description

The PicoLO laser system 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 Nd:YAG Picosecond Laser System 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 laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.
1064nm
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.
532nm
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.

## 6. Technical Characteristics in Comparison to Predicate Devices

PicoLO Nd:YAG Picosecond Laser System is substantially equivalent to the following legally marketed predicate device.

| | **Predicate Device** | **Proposed Device** |
|---|---|---|
| 510(K) Number | K170597 | N/A |
| Product Code | GEX | GEX |
| Classification / Regulation | Class II/878.4810 | Class II/878.4810 |
| Manufacturer | Syneron Candela Corporation | Laseroptek Co.,Ltd. |
| Device Name | PicoWay Laser System | PicoLO Nd:YAG Picosecond Laser System |
| Clearance Date | 25 May 2017 | N/A |
| Intended Use / Indications for Use: | The PicoWay laser system is indicated for the following at the specified wavelength:<br>532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.<br>785nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. | PicoLO laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.<br>1064nm<br>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. |

| | | |
|---|---|---|
| | 1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.<br><br>The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.<br><br>The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.<br><br>The Resolve handpieces are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV. | 532nm<br><br>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. |
| Wavelength | 532nm, 1064nm<br>785 nm | 1064/532 nm (Accuracy ±20%) |
| Pulse Duration (Pulse Width) | 450ps (1064nm)<br>375ps (532nm) | 450ps (1064nm), (Accuracy ±20%)<br>380ps (532nm), (Accuracy ±20%) |
| Pulse Energy (max) | 400mJ (1064nm)<br>200mJ (532nm) | 500mJ (1064nm), (Accuracy ±20%)<br>350mJ (532nm), (Accuracy ±20%) |
| Peak Power (Gigawatts) | Up to 0.9 | 1.1 |
| Aiming Beam | Unknown | Laser diode, 635nm/ <5mW |
| Repetition Rate (Hz) | Single, 1-10 Hz (1064nm and 532 nm) | Single, M3, M5, 1~10Hz (Accuracy: ± 20%) |
| Spot size (mm) | Zoom 2-10 mm (1064nm and 532nm)<br>Fractional and non-fractional 1064 (6x6 $mm^2$)<br>Fractional and non-fractional 532 (6x6 $mm^2$) | 1064 (10 mm)<br>532 (7 mm)<br>Collimator (20 mm)<br>Zoom (2~7 mm) |
| Laser Type | Q-switched Nd:YAG Laser | Q-switched Nd:YAG Laser |
| Activation | Via foot-switch | Via foot-switch |
| Display | LCD Touch screen | TFT LCD Touch screen |
| Cooling System | Unknown | Internal water to air heat exchanger |
| Electrical Power | 200-240 VAC, 50/60 Hz, 30 A, 4600 VA single | 220-230VAC, 50/60Hz |
| Beam Delivery System | Articulated Arm with Handpiece | Articulated Arm with Handpiece |
| System Dimensions(mm) | 1070 (H) x 460 (W) x 690 (D) | 350(W) x 1080(L) x 970(H) |
| System Weight (kg) | 125 kg | 110 kg |

**6. Performance Data**

Non-clinical tests: Testing conducted on the PicoLO Nd:YAG Picosecond 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 standards:

- PicoLO Nd:YAG Picosecond Laser System 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: 2007. All the results presented here demonstrated the requirements and tests for electromagnetic disturbances.
- PicoLO Nd:YAG Picosecond Laser System 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 Nd:YAG Picosecond 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 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.

**7. Substantial Equivalence**

PicoLO Nd:YAG Picosecond Laser System and the predicate device are both intended for prescription use. The intended use of PicoLO Nd:YAG Picosecond Laser System is within the scope of the predicate device. The predicate device produces 3 wavelengths which are 1064 nm, 532 nm and 785 nm, while the proposed device produces dual wavelength which are 1064 nm and 532 nm. The wavelengths of the proposed device's wavelengths are within the scope of the predicate device. When compare at the same wavelength, the laser parameter of the proposed device is very similar.

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

## 8. Conclusions

The technological characteristics of the subject device PicoLO Nd:YAG Picosecond Laser System are comparable to those of the predicates for comparable indications for use. Thus, subject device PicoLO is concluded to be substantially equivalent to the predicates.