May 22, 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: K230373
Trade/Device Name: HELIOS 785 Pico
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: April 21, 2023
Received: April 21, 2023

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)*
K230373

Device Name
HELIOS 785 Pico

Indications for Use *(Describe)*
[Indication for use of Q-switched Nd:YAG Laser]
- Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064nm)
- Removal or lightening of unwanted hair with or without adjuvant preparation (1064nm)
- Tattoo Removal (1064nm, 532nm)
dark ink : blue and black (1064nm)
light ink : red, sky blue, green (532nm)

- Treatment of Benign Vascular Lesions (532nm)
port wine birthmarks
telangiectaias
spider angioma
cherry angioma
spider nevi

- Treatment of Benign Pigmented Lesions (1064nm, 532nm)
café-au-lait birthmarks (532nm)
solar lentiginos (532nm)
senile lentiginos (532nm)
becker's nevi (532nm)
freckles (532nm)
nevus spilus (532nm)
nevus of ota (1064nm)

[Indication for use of Ti:Sapphire Laser]
Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. (785nm)

Q-switched Nd:YAG Laser and Ti:Sapphire Laser cannot be used simultaneously.

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.

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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:	Wonmi Lee, BT Solutions, Inc.
Address:	904, Eonju-ro 86-gil 5, Gangnam-gu, Seoul, 06210 Republic of Korea (South Korea) Tel: +82.2.538.9140 Email: wmlee@btsolutions.co.kr
Preparation Date:	May 16, 2023

2. Identification of the Proposed Device

Trade/Device Name:	HELIOS 785 Pico
Common Name:	Q-switched Nd:YAG and Gain switched Ti:sapphire Laser System
Classification Name:	Powered Laser Surgical Instrument
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product Code:	GEX

3. Identification of the Predicate Device

Predicate Type	510(k) Number	Device Name	Applicant
Primary Predicate	K212663	HELIOS IV 785	Laseroptek Co., Ltd.
Reference Predicate	K191685	PicoWay Laser System	Syneron Candela Corporation

4. Device Description

HELIOS 785 Pico consists of a Q-switched Nd:YAG (1064 nm) laser, frequency doubled KTP Nd:YAG (532 nm) laser, and Ti:Sapphire laser (785 nm). The device consists of a main body, color touch screen, articulated arm, foot switch and several handpieces, and is controlled by an embedded processor. The device uses focusing optics to deliver a pattern of thermal energy to the epidermis and dermis to achieve its intended purpose. It is for prescription use only.

5. Indications / Intended Use

[Indication for use of Q-switched Nd:YAG Laser]
- Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064nm)
- Removal or lightening of unwanted hair with or without adjuvant preparation (1064nm)

- Tattoo Removal (1064nm, 532nm)
  - dark ink : blue and black (1064nm)
  - light ink : red, sky blue, green (532nm)

- Treatment of Benign Vascular Lesions (532nm)
  - port wine birthmarks
  - telangiectaias
  - spider angioma
  - cherry angioma
  - spider nevi

- Treatment of Benign Pigmented Lesions (1064nm, 532nm)
  - café-au-lait birthmarks (532nm)
  - solar lentiginos (532nm)
  - senile lentiginos (532nm)
  - becker's nevi (532nm)
  - freckles (532nm)
  - nevus spilus (532nm)
  - nevus of ota (1064nm)

[Indication for use of Ti:Sapphire Laser]
Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. (785nm)

Q-switched Nd:YAG Laser and Ti:Sapphire Laser cannot be used simultaneously.

6. Substantial Equivalence Comparison

Comparison of the Indications for Use: Indications for use statement of the subject and primary predicate devices are comparable.

Comparison of Technology:

	Predicate Device	**Subject Device**
510(K) Number	K212663	K230373
Wavelength (nm) (Accuracy ±20%)	1064 532 785	1064 532 785
Pulse Duration (max)	5-10 ns @ 1064 nm 5-10 ns @ 532 nm 600 ps @ 785 nm	5-10 ns @ 1064 nm 5-10 ns @ 532 nm 600 ps @ 785 nm
Pulse Energy (max)	1.4 J @ 1064 nm 0.5 J @ 532 nm 0.2 J @ 785 nm	1.4 J @ 1064 nm 0.5 J @ 532 nm 0.2 J @ 785 nm
Fluence (J/cm^2, max)*	8 @ 1064nm 8 @ 532 nm 4 @ 785 nm	8 @ 1064nm 8 @ 532 nm 4 @ 785 nm
Peak Power (GW)	0.28 @ 1064 nm 0.1 @ 1064 nm 0.33 @ 785 nm	0.28 @ 1064 nm 0.1 @ 1064 nm 0.33 @ 785 nm

Max. Average Power (W)	14 @ 1064 nm 5 @ 1064 nm 2 @ 785 nm	14 @ 1064 nm 5 @ 1064 nm 2 @ 785 nm
Spot Size (mm)	1-10 @ 1064 nm 1-10 @ 532 nm 1-8 @ 785 nm	1-10 @ 1064 nm 1-10 @ 532 nm 1-8 @ 785 nm
Repetition Rate (Hz)	1-10 @ 1064 nm 1-10 @ 532 nm 1-5 @ 785 nm	1-10 @ 1064 nm 1-10 @ 532 nm 1-10 @ 785 nm
Display	TFT LCD Touch screen	TFT LCD Touch screen
Electrical Power	220-230VAC, 50/60Hz	220-230VAC, 50/60Hz
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece
System Dimensions(mm)	936(H) x298(W) x 819(D)	936(H) x298(W) x 819(D)
System Weight (kg)	80	80

*Maximum fluence is not available for all spot sizes.

All but one (i.e., repetition rate) technological features of the subject device are comparable to the corresponding technological features of the predicate device. Additional information is provided (i.e., technological characteristics of the reference predicate) to support the argument that doubling the repetition rate for the 785 nm laser is not expected to adversely affect the device performance or patient safety for the proposed intended use.

7. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device conforms to the relevant mandatory performance standards for laser products 21 CFR 1040.10 and 1040.11, met all design specifications, and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility
- IEC 60601-2-22:2012, Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
- IEC 60825-1: 2014, Safety of laser products - Part 1: Equipment classification and requirements
- Biocompatibility evaluation per ISO 10993 and FDA guidance
- Usability per IEC 60601-1-6 and IEC 62366
- Risk management per ISO 14971
- Software Validation & Verification Test
- Bench Testing to verify the performance.

8. Clinical Testing

No clinical study is included in this submission.

9. Substantial Equivalence

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.