June 9, 2022

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

Re: K212663
Trade/Device Name: Helios Iv 785
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: May 4, 2022
Received: May 5, 2022

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,

For 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)*
K212663

Device Name
HELIOS IV 785

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

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5. 510(k) Summary

K212663

1. General Information

Applicant/Submitter:	Laseroptek Co., Ltd.
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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:	June 7, 2022

2. Device Name and Code

Device Trade Name:	HELIOS IV 785
Common Name:	Q-switched Nd:YAG and Gain switched Ti:sapphire 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

3. Predicate Device

HELIOS IV 785 is substantially equivalent to the following devices:

Table 5.1 Predicate device

Applicant	Device Name	510(k) Number
Laseroptek Co., Ltd.	Helios III Q-Switched Nd:YAG Laser System	K152856
Syneron Candela Corporation	PicoWay Laser System	K170597

4. Device Description

HELIOS IV 785 consist of a set of Q-switched Nd:YAG (1064 nm) laser, frequency doubled KTP Nd:YAG (532 nm) laser, and Ti:Sapphire laser (785 nm), and 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

[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 Vascular Lesions (532nm)

  - port wine birthmarks
  - telangiectaias
  - spider angioma
  - cherry angioma
  - spider nevi

- Treatment of 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. Technical Characteristics in Comparison

HELIOS IV 785 is substantially equivalent to the following legally marketed predicate devices.

Two predicates were cited to support substantial equivalence for the proposed indications for use.

6.1. Technical Characteristics in Comparison with the Predicate device (1)

HELIOS IV 785 is substantially equivalent to the predicate device (K152856) for Q-switched Nd:YAG (1064 nm) laser and frequency doubled KTP Nd:YAG (532 nm) laser.

Table 5.2 Comparison table between Predicate device (1) and Proposed device

	Predicate Device (1)	**Proposed Device**
510(K) Number	K152856	K212663
Product Code	GEX	GEX
Classification / Regulation	Class II/878.4810	Class II/878.4810
Manufacturer	Laseroptek Co.,Ltd.	Laseroptek Co.,Ltd.
Device Name	Helios III	HELIOS IV 785
Clearance Date	July 17, 2015	N/A
Intended Use / Indications for Use:	The Helios III Q-Switched Nd:YAG Laser System delivers pulse wave laser light in the contact or noncontact mode for; - Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm) - Removal or lightening of unwanted hair with or without adjuvant preparation (1064 nm)	[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 Vascular Lesions: (532nm) • port wine birthmarks • telangiectasias • spider angioma • cherry angioma • spider nevi - Treatment of 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)	- Tattoo Removal (1064nm, 532nm) • dark ink : blue and black (1064nm) • light ink : red, sky blue, green (532nm) - Treatment of Vascular Lesions (532nm) • port wine birthmarks • telangiectaias • spider angioma • cherry angioma • spider nevi - Treatment of 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.*
Wavelength	1064,532 nm (Accuracy ±20%)	1064,532, 785mm (Accuracy ±20%)
Pulse Duration (max)	10 ns	10 ns
Pulse Energy (max)	1.3 J (0.5J @ 532 nm) / pulse	1.4 J (0.5J @ 532 nm) / pulse
Fluence	1 – 8 J/cm2 @1 to 8mm spot size	1 – 8 J/cm2 @1 to 10mm spot size
Peak Power (Gigawatts)	0.260 (1064nm) 0.100 (532nm)	0.280 (1064nm) 0.100 (532nm)
Spot size (mm)	Up to 8 mm	Up to 10 mm
Repetition Rate	Single Shot, 1~10 Hz	Single, 1~10Hz (Accuracy: ± 20%) (1064nm, 532nm)
Laser Type	Q-switched Nd:YAG	Q-switched Nd:YAG and Ti:sapphire
Activation	Via foot-switch	Via foot-switch
Display	TFT LCD Touch screen	TFT LCD Touch screen
Electrical Power	AC 230 V, 50/60 Hz	220-230VAC, 50/60Hz
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece

System Dimensions(mm)	935(H) X 297(W) X 818(D)	936(H) x298(W) x 819(D)
System Weight (kg)	80	80

6.2. Technical Characteristics in Comparison with the Predicate device (2)

HELIOS IV 785 is substantially equivalent to the predicate device (K170597) for the Ti:sapphire laser(785nm).

Table 5.3 Comparison table between Predicate device (2) and Proposed device

	Predicate Device (2)	**Proposed Device**
510(K) Number	K170597	K212663
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	HELIOS IV 785
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: 532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. **785nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.** 1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V. The Resolve handpieces are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.	[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 Vascular Lesions (532nm) • port wine birthmarks • telangiectaias • spider angioma • cherry angioma • spider nevi - Treatment of 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.*
Wavelength	1064nm, 532nm, 785 nm	1064mm,532 nm, 785mm (Accuracy ±20%)
Pulse Duration (max)	240 - 750 (ps)	600ps
Pulse Energy (max)	450mJ (1064nm) 220mJ (532nm) 120mJ (785nm)	200mJ (785nm)
Fluence	0.16 – 4.0 J/cm^2	Spot size 1mm : 4.0J/cm^2 Spot size 2mm : 4.0J/cm^2 Spot size 3mm : 2.8J/cm^2 Spot size 4mm : 1.5J/cm^2 Spot size 5mm : 1.0J/cm^2 Spot size 6mm : 0.7J/cm^2 Spot size 7mm : 0.5J/cm^2 Spot size 8mm : 0.3J/cm^2
Peak Power (Gigawatts)	0.9 (1064nm) 0.6 (532nm) 0.4 (785nm)	0.33 (785nm)
Spot size (mm)	up to 10 mm	Up to 8mm
Repetition Rate (Hz)	Single, 10 Hz (1064 nm, 532 nm) or 5 Hz (785 nm)	Single, 1~5Hz (Accuracy: ± 20%) (785nm)
Laser Type	Q-switched Nd:YAG and Ti:sapphire	Q-switched Nd:YAG and Ti:sapphire
Activation	Via foot-switch	Via foot-switch
Display	LCD Touch screen	TFT LCD Touch screen
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)	936(H) x298(W) x 819(D)
System Weight (kg)	125	80

7. Performance Data

Non-clinical tests: Testing conducted on the HELIOS IV 785 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:

- HELIOS IV 785 is tested and evaluated according to IEC 60601-1:2005+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.

- HELIOS IV 785 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.
- HELIOS IV 785 is tested and evaluated according to FDA-recognized consensus standard IEC 60601-2-22:2019. 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. 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 10993-5:2009and ISO 10993-10:2013.

8. Substantial Equivalence

The HELIOS IV 785, subject of this submission, is a modification of the Helios III Q-Switched Nd:YAG Laser System cleared under K152856. The modification is about adding the Ti:Sapphire laser (785 nm) in the previous Q-switched Nd:YAG laser system.

Based upon the predicted overall performance characteristics for the HELIOS IV 785, Laseroptek Co. Ltd. believes that no significant differences exist in usage of its underlying technological principles between HELIOS IV 785 and the predicate devices.

9. Conclusions

The technological characteristics of the subject device HELIOS IV 785 are comparable to the predicate devices for indications for use. Thus, subject device HELIOS IV 785 is concluded to be substantially equivalent to the predicate devices.