February 7, 2025

Laseroptek Co., Ltd.
% Kim Do Hyun
CEO
BT Solutions, Inc.
Unit 303, Gonghang-daero 337, Gangseo-gu
Seoul, Seoul 07590
Korea, South

Re: K243780
Trade/Device Name: HELIOS 785 Pico (1754V2)
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 9, 2024
Received: December 9, 2024

Dear Kim Do Hyun:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.07 22:25:46 -05'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243780

Device Name
HELIOS 785 Pico (1754V2)

Indications for Use *(Describe)*

[Indications for use of Q-switched Nd:YAG Laser]
1064 nm (including RTP 1064 mode):
- Incision, excision, ablation, vaporization of soft tissue for general dermatology
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment melasma
- Treatment of Pigmented Lesions
  • nevus of ota
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Tattoo Removal
  • dark ink: black, blue and brown

532 nm:
- Treatment of Vascular Lesions
  • port wine birthmarks
  • telangiectaias
  • spider angioma
  • cherry angioma
  • spider nevi
- Treatment of Pigmented Lesions
  • café-au-lait birthmarks
  • solar lentiginos
  • senile lentiginos
  • becker's nevi
  • freckles
  • nevus spilus
  • nevus of ota
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Tattoo Removal
  • light ink: red, sky blue, green, tan, purple, and orange

[Indications for use of FR mode in Nd:YAG Laser]
- Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB (Pseudofolliculitis Barbae). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles

[Indications 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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510(k) Summary K243780

1 General Information

Applicant/Submitter:	Laseroptek Co., Ltd.
Address:	Hyundai I Valley 114,116,117,203,204, 31, Galmachi-ro 244beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
Contact Person:	Do Hyun Kim, BT Solutions, Inc.
Address:	Unit 303, Gonghang-daero 337, Gangseo-gu Seoul, 07590, Republic of Korea Tel: +82-2-538-9140 Email: ceo@btsolutions.co.kr
Preparation Date:	February 4, 2025

2 Device Name and Code

Device Trade Name:	HELIOS 785 Pico
Model Name:	1754V2
Common Name:	Q-switched Nd:YAG + Gain switched Ti:sapphire Laser System
Classification Name:	Powered laser surgical instrument
Product Code:	GEX
Regulation Number:	878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery

3 Technical Characteristics in Comparison to Predicate Devices

The HELIOS 785 Pico, is substantially equivalent to the following legally marketed predicate devices: HELIOS 785 Pico (1754V1) (K230373) and Finebeam (K202288);

Table 1 Comparison of the proposed device to the primary predicate device

	Predicate Device (1)	**Proposed Device**
510(K) Number	K230373	K243780
Product Code	GEX	GEX
Classification / Regulation	Class II/878.4810	Class II/878.4810
Manufacturer	Laseroptek Co.,Ltd.	Laseroptek Co.,Ltd.

Device Name	HELIOS 785 Pico	HELIOS 785 Pico
Model No.	1754V1	1754V2
Intended Use / Indications for 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.*	[Indications for use of Q-switched Nd:YAG Laser] 1064 nm(including RTP 1064 mode): - Incision, excision, ablation, vaporization of soft tissue for general dermatology - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment melasma - Treatment of Pigmented Lesions nevus of ota - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Tattoo Removal dark ink: black, blue and brown 532 nm: - Treatment of Vascular Lesions port wine birthmarks telangiectaias spider angioma cherry angioma spider nevi - Treatment of Pigmented Lesions café-au-lait birthmarks solar lentiginos senile lentiginos becker's nevi freckles nevus spilus - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Tattoo Removal light ink: red, sky blue, green, tan, purple, and orange

		[Indications for use of FR mode in Nd:YAG Laser] - Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB (Pseudofolliculitis Barbae). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins - Coagulation and hemostasis of soft tissue - Treatment of wrinkles [Indications for use of Ti:Sapphire Laser] 785 nm: - Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. *Q-switched Nd:YAG Laser and Ti:Sapphire Laser cannot be used simultaneously.*
Wavelength	1064 mm, 532 mm, 785 mm	1064 mm, 532 mm, 785 mm
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 5-10 ns @ RTP mode(1064nm)[5)] 300 us @ FR mode(1064 nm) [5)]
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 2.0 J @ RTP mode(1064 nm) [5)] 3.0 J @ FR mode(1064 nm) [5)]

Spot size (mm)	- Zoom Collimator (1064, 532 nm) 1~10 mm - Zoom (1064, 532 nm) 1~7 mm - 1064 FX 5 mm x 5 mm - 532 FX 4 mm x 4 mm - DIA FX 785 (785 nm) 8 mm x 8 mm - DIA FX 785 (785 nm) 5 mm x 5 mm - 785 Zoom (785 nm) 1 mm x 1 mm ~ 7 mm x 7 mm - 785 Colimator (785 nm) 7 mm x 7 mm	- Zoom Collimator (1064, 532 nm) 5~10 mm - Zoom (1064, 532 nm) 1~7 mm - 1064 FX 5 mm x 5 mm - 532 FX 4 mm x 4 mm - DIA FX 785 (785 nm) 8 mm x 8 mm - DIA FX 785 (785 nm) 5 mm x 5 mm - 785 Zoom (785 nm) 1 mm x 1 mm ~ 7 mm x 7 mm - 785 Colimator (785 nm) 7 mm x 7 mm
Repetition Rate (Hz)	1-10 @ 1064 nm 1-10 @ 532 nm 1-10 @ 785 nm	1-10 @ 1064 nm 1-10 @ 532 nm 1-10 @ 785 nm
Laser Type	Q-switched Nd:YAG and Ti:sapphire	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	220-230 V~, 50/60 Hz	220-230 V~, 50/60 Hz
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

Table 2 Comparison of the proposed device to the secondary predicate device.

	Predicate Device(2)	**Proposed Device**
510(K) Number	K202288	K243780
Product Code	GEX	GEX
Classification / Regulation	Class II/878.4810	Class II/878.4810
Manufacturer	SNJ Co., Ltd.	Laseroptek Co.,Ltd.
Device Name	Finebeam	HELIOS 785 Pico

Model No.	-	1754V2
Intended Use / Indications for Use:	[532nm single and 1064nm single function in the Q-switched mode] With 1064nm single or 1064nm PDP function - Removal dark ink (black, blue and brown) tattoos - Treatment melasma - Treatment nevus of Ota - Treatment common nevi - Removal of lightening of unwanted hair - Skin resurfacing procedures for the treatment of acne scars and wrinkles With 532nm single function - Removal of light ink (red, tan, purple, and orange) tattoos - Treatment of vascular lesions including, but not limited to port-wine stains, telangiectasias, spider angioma, cherry angioma - Treatment of pigmented lesions including, but not limited to cafe-au-Lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, freckles, common nevi, and nevus spilus - Treatment of seborrheic keratosis - Treatment of post-inflammatory hyperpigmentation - Skin resurfacing procedures for the treatment of acne scars and wrinkles [Non-Q-Switched function in the Q-Switched mode] With 1064nm Non-QSW function - Removal of unwanted hair, for stable long term or permanent	[Indications for use of Q-switched Nd:YAG Laser] 1064 nm(including RTP 1064 mode): - Incision, excision, ablation, vaporization of soft tissue for general dermatology - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment melasma - Treatment of Pigmented Lesions nevus of ota - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Tattoo Removal dark ink: black, blue and brown 532 nm: - Treatment of Vascular Lesions port wine birthmarks telangiectaias spider angioma cherry angioma spider nevi - Treatment of Pigmented Lesions café-au-lait birthmarks solar lentiginos senile lentiginos becker’s nevi freckles nevus spilus - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Tattoo Removal light ink: red, sky blue, green, tan, purple, and orange

	hair reduction and treatment of PFB (Pseudofolliculitis Barbae). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins - Coagulation and hemostasis of soft tissue - Treatment of wrinkles	[Indications for use of FR mode in Nd:YAG Laser] - Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB (Pseudofolliculitis Barbae). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins - Coagulation and hemostasis of soft tissue - Treatment of wrinkles [Indications for use of Ti:Sapphire Laser] 785 nm: - Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. *Q-switched Nd:YAG Laser and Ti:Sapphire Laser cannot be used simultaneously.*
Wavelength	1064 nm, 532 nm	1064 mm, 532 mm, 785 mm
Pulse Duration (max)	<25 ns @ 1064 single (Q-switched mode) <25 ns @ 532 single (Q-switched mode) <25ns @ PDP mode(1064 nm) 300 us @ non-Q switched mode(1064 nm)	5-10 ns @ 1064 nm 5-10 ns @ 532 nm 600 ps @ 785 nm 5-10 ns @ RTP mode(1064nm) 300 us @ FR mode(1064 nm)

Pulse Energy (max)	1.6 J @ 1064nm 0.5 J @ 532nm 2.2 J @ PTP mode(1064 nm) 3.5 J @ Non-Q mode(1064 nm)	1.4 J @ 1064 nm 0.5 J @ 532 nm 0.2 J @ 785 nm 2.0 J @ RTP mode(1064 nm) 3.0 J @ FR mode(1064 nm)
Spot size (mm)	- Collimator Handpiece 8 mm (1064 nm) - Zoom Handpiece 2~10 mm(1064 nm), 1~7 mm (532 nm)	- Zoom Collimator (1064, 532 nm) 5~10 mm - Zoom (1064, 532 nm) 1~7 mm - 1064 FX 5 mm x 5 mm - 532 FX 4 mm x 4 mm - DIA FX 785 (785 nm) 8 mm x 8 mm - DIA FX 785 (785 nm) 5 mm x 5 mm - 785 Zoom (785 nm) 1 mm x 1 mm ~ 7 mm x 7 mm - 785 Colimator (785 nm) 7 mm x 7 mm
Repetition Rate	Unknown	1-10 @ 1064 nm 1-10 @ 532 nm 1-10 @ 785 nm

4 Device Description

The flash lamp as a laser pumping source converts electric energy to light energy when a high voltage is applied. Nd:YAG crystal with the specific resonator emits an 1064nm single wavelength laser by absorbing light energy from the flash lamp. Q-switching mode is applied to the 1064nm laser resonator to amplify the 1064nm laser with about 10ns short pulse width.

The amplified Q-switched 1064nm laser is secondarily amplified by an another Nd:YAG crystal and, then is converted to a second harmonic 532nm laser by passing through KTP crystal.
Finally a 785nm laser is emitted by the 785nm cavity with Ti:Sapphire crystal using the 532nm laser as a laser pumping source.
HELIOS 785 Pico Laser System can emit 1064nm, 532nm, and 785nm laser selectively by switching the wavelength conversion optical modules. The 1064nm laser is emitted by only Nd:YAG crystal resonator and the 532nm laser can be emitted with the 1064nm laser and KTP crystal. The 785nm laser can be emitted by all optical modules.

The Q-switch mode normally produces polarized light, but it is also possible to set the FR(Free Running) mode, which emits light in all directions by removing the optics of the Q-switch module. Additionally, the RTP(Real Twin Pulse) mode can be set to generate two identical pulses with a very short interval instead of a single pulse.

The HELIOS 785 Pico laser system consists of:
a) A high voltage power supply, which converts and rectifies Alternating Current (AC) to provide regulated power for the flashlamp simmer current and main triggering pulse.
b) A cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger.
c) The micro processor based controller unit, which regulates the functions of both lasers and allows parameter selection by the user.
d) The Nd:YAG laser + Ti:sapphire laser head.

5 Indications / Intended Use

[Indications for use of Q-switched Nd:YAG Laser]
1064 nm(including RTP 1064 mode):
- Incision, excision, ablation, vaporization of soft tissue for general dermatology
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment melasma
- Treatment of Pigmented Lesions
  nevus of ota
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Tattoo Removal
  dark ink: black, blue and brown

532 nm:
- Treatment of Vascular Lesions
  port wine birthmarks
  telangiectaias
  spider angioma
  cherry angioma
  spider nevi
- Treatment of Pigmented Lesions

café-au-lait birthmarks
solar lentiginos
senile lentiginos
becker's nevi
freckles
nevus spilus
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Tattoo Removal
light ink: red, sky blue, green, tan, purple, and orange

[Indications for use of FR mode in Nd:YAG Laser]
- Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB (Pseudofolliculitis Barbae). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles

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

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

6 Performance Data

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

- Basic safety and essential performance is tested and evaluated according to the FDA-recognized consensus standard, ES 60601-1.
- 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: 2014.
- Risk management was recorded by referring to ISO 14971.
- Usability was documented by referring to IEC 60601-1-6.
- Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment is evaluated in accordance with IEC 60601-2-22.

7 Substantial Equivalence

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 HELIOS 785 Pico, Laseroptek Co., Ltd.. believes that no significant differences in usage of its underlying technological principles between HELIOS 785 Pico and the predicate device.

8 Conclusions

On the basis of the information provided in this Summary, Laseroptek Co., Ltd. believes that HELIOS 785 Pico (1754V2) is substantially equivalent to legally commercialized predicate devices (K230373 and K202288) for the purposes of this 510 (k) submission.