DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 2, 2016

Laseroptek Co. Ltd.
Mr. Kevin J. Choi
28 Stafford Drive
West Windsor, NJ 08550

Re: K152856
Trade/Device Name: Helios III
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 5, 2016
Received: April 12, 2016

Dear Mr. Choi:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152856

Device Name

Helios III Q-Switched Nd:YAG Laser System

Indications for Use *(Describe)*

Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm)
Removal or lightening of unwanted hair with or without adjuvant preparation (1064nm)
Tattoo Removal: Dark ink (blue and black) (1064 nm)
Tattoo Removal: light ink (red, sky blue, green) (532 nm)
port wine birthmarks (532 nm)
telangiectasias (532 nm)
spider angioma (532 nm)
cherry angioma (532 nm)
spider nevi (532 nm)
cafe-au-lait birthmarks (532 nm)
solar lentiginos, senile lentiginos, becker's nevi, freckles, nevus spilus (532 nm)
nevus of ota (1064 nm)

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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This 510(k) Summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR §807.92

Submitter's Information

Applicant:	Laseroptek Co. Ltd.
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Preparation Date:	07/17/2015
Device Trade Name:	Helios III
Common Name:	Q-Switched Nd:YAG Laser
Classification Name:	Instruments, Surgical, Powered, Laser 79-GEX (21 CFR §878-4810)
Legally Marketed Predicate Devices:	• Cynosure, Inc.'s Revlite Q-Switched Nd:YAG Laser System (K133254) • Laseroptek Co. Ltd.'s Helios II Q-Switched Nd:YAG Laser System (K083203)

Intended Use of Helios III:

The Helios III Q-Switched Nd:YAG Laser System delivers pulse wave laser light in the contact or non-contact 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)

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)

Device Description:

The Helios III laser system is based on the Nd:YAG (1064 nm) and frequency doubled KTP Nd:YAG (532 nm) laser technology. Three basic elements of operations are as follows:

1) A Nd:YAG crystal is used as a gain medium which produces a laser beam.

2) A resonator then amplifies the beam.

3) A lamp that contains Xe gas is used, as a pumping

	light source. The lamp requires a high-pressure power source device for operation. When the electric energy generated from the high-pressure power source is induced into the electrode of the lamp, it converts into light energy. This converted light energy pumps the Nd:YAG crystal – a gain medium – and the light exhausted from the crystal is amplified into a specific wavelength light. As it passes between the resonant gases, laser beam radiates to an output unit. The regulation of laser output and repetition rate can be set by the user via GUI (Graphic User Interface) and controlled by microprocessor, which interfaces with the power supply.
Performance Data:	Non-clinical testing of Helios III included visual and mechanical inspection, electrical and mechanical safety testing, functional performance testing, etc., in bench. Some of these tests include visual inspection, earthbond testing, software testing, transit testing, leakage current testing and measurements. Test reports have been submitted.
Substantial Equivalence	Helios III's intended use is identical to the intended use of the predicate devices: *Cynosure, Inc.'s Revlite Q-Switched Nd:YAG Laser System (K133254)* and *Laseroptek Co. Ltd.'s Helios II Q-Switched Nd:YAG Laser System (K083203)* Comparison of indications for use and performance specifications are provided in the following tables.

	Predicate Device	Predicate Device	Proposed Device
510(K) Number	K133254	K083203	K152856
Manufacturer	Cynosure (HOYA ConBio)	Laseroptek Co. Ltd.	Laseroptek Co. Ltd.
Device Name	RevLite Q-Switched Nd:YAG Laser System	Helios II Q-Switched Nd:YAG Laser System	Helios III Q-Switched Nd:YAG Laser System
Intended Use / Indications for Us:			
	Tattoo Removal (dark ink: blue and black)	Tattoo Removal (dark ink: blue and black)	Tattoo Removal (dark ink: blue and black)
	Dermal pigmented legions, including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Café-au-lait	Dermal pigmented legions: Nevus of Ota, Café-au-lait birthmarks, solar lentiginos, senile lentiginos, becker's nevi, freckles, and nevus spilus	Dermal pigmented legions: Nevus of Ota, Café-au-lait birthmarks, solar lentiginos, senile lentiginos, becker's nevi, freckles, and nevus spilus
	Removal or lightening of hair with or without adjuvant preparation	Removal or lightening of hair with or without adjuvant preparation	Removal or lightening of hair with or without adjuvant preparation
	Skin resurfacing for acne scars and wrinkles	Incision, excision, ablation, vaporization of soft tissue for general dermatology	Incision, excision, ablation, vaporization of soft tissue for general dermatology
	Benign cutaneous lesions: including, but not limited to; striae and scars (excludes the 650 nm wavelength)	Tattoo Removal (light ink: red, sky blue, green)	Tattoo Removal (light ink: red, sky blue, green)
	Reduction of red pigmentation in hypertrophic and deloid scars where vascularity is an integral part of the scar (excludes the 650 nm wavelength)	Treatment of vascular lesions: port wine, birthmarks, telangiectasias, spider angioma, cherry angioma, and spider nevi	Treatment of vascular lesions: port wine, birthmarks, telangiectasias, spider angioma, cherry angioma, and spider nevi
	Tattoo Removal (light ink: red, sky blue, green)		
	Vascular lesions including but not limited to: port wine, birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi		
	Epidermal pigmented lesions; including, but not limited to: café-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis		
	Skin resurfacing for acne scars and wrinkles		
	Benign cutaneous lesions; including, but not limited to: striae and scars (excludes the 650 nm wavelength)		
	Reduction of red pigmentation in hypertrophic and deloid scars where vascularity is an integral part of the scar (excludes the 650 nm wavelength)		

Table 1: Approved Indication of Uses for Helios III Predicate Devices

	Predicate Device	Predicate Device	Proposed Device
510(K) Number	K133254	K083203	K152856
Manufacturer	Cynosure (HOYA ConBio)	Laseroptek Co. Ltd.	Laseroptek Co. Ltd.
Device Name	RevLite Q-Switched Nd:YAG Laser System	Helios II Q-Switched Nd:YAG Laser System	Helios III Q-Switched Nd:YAG Laser System
Clearance Date:	3/5/2014	4/28/2009	Not Available
Classification / Regulation	21 CFR 878.4810 (GEX)	21 CFR 878.4810 (GEX)	21 CFR 878.4810 (GEX)
Laser Medium	Nd:YAG	Nd:YAG	Nd:YAG
Operating Parameters	Q-Switched	Q-Switched	Q-Switched
Wavelength	1064 nm / 532 nm	1064 nm / 532 nm	1064 nm / 532 nm
Pulse Characteristics:			
Maximum Pulse Duration	7 – 20 ns	8 ns	10 ns
Energy Delivered	1.6 J	1 J (0.5 J@ 532 nm) / pulse	1.3 J (0.5J @ 532 nm) / pulse
Fluence	1 – 8 J/cm2 @ 3 – 8 mm spot size	1 – 8 J/cm2 @ 1 to 7 mm spot size	1 – 8 J/cm2 @ 1 to 8 mm spot size
Spot Sizes	2 – 8.5 mm range with 0.1 mm increments	1 – 7 mm	(1064) 5 mm (532) 4 mm (Collimator) 8 mm (Zoom) 1~7 mm
Repetition Rate	Single shot, 1 - 10 Hz	Single Shot, 1 – 10 Hz	Single Shot, 1 – 10 Hz
Average Power (Max):	10 W (5 W @ 532 nm)	10 W (5 W @ 532 nm)	13 W (5W @ 532 nm)
Physical Characteristics:			
System Dimensions	31.8”(H) X 12” (W) X 28.5” (D)	37.2”(H) X 13”(W) X 37.2 (D)	36.8”(H) X 11.7”(W) X 32.2” (D)
System Weight	131 lbs.	154 lbs.	176 lbs.
Electrical Requirements	AC 230 V, 50/60 Hz	AC 230 V, 50/60 Hz	AC 230 V, 50/60 Hz
Maximum Power	20W	20 W	20W

Table 2: Performance Specification Comparison with Predicate Devices

Conclusion

The Helios III Q-Switched Nd:YAG Laser System is substantially equivalent to other existing systems in commercial distribution for treatment of the intended use indications share very similar / exactly same performance specification parameters as noted in above table.