March 26, 2025

Laseroptek Co., Ltd.
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K182045
Trade/Device Name: Lotus III Multi-Pulsed Er: Yag 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

Dear Mark Job:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 27, 2018. Specifically, FDA is updating this SE Letter to include a signature as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Tanisha Hithe, OHT4: Office of Surgical and Infection Control Devices, 301-796.5524, Tanisha.Hithe@fda.hhs.gov.

Sincerely,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.03.26 10:53:34 -04'00'

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

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

Re: K182045
Trade/Device Name: Lotus III Multi-Pulsed Er: YAG 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,

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)*
N/A

K182045

Device Name
LOTUS III Multi-Pulsed Er:YAG Laser System

Indications for Use *(Describe)*
The LOTUS III Multi-Pulsed Er:YAG Laser System is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 Galmachi-*Ro*, Jungwon-*Gu* Seongnam-*Si*, Gyeonggido, 13212 Rep. of Korea (South Korea) Tel) +82.31.8023.5150 Fax) +82.31.8023.5151
Contact Person:	Mina Joo, BT Solutions, Inc.
Address:	Unit 402, 91-14 Seolleung-ro, Gangnam-gu, Seoul, Republic of Korea Tel) +82.2.538.9140 Email) smanager@btsolutions.co.kr
Preparation Date:	December-17-2018

2. Device Name and Code

Device Trade Name:	LOTUS III Multi-Pulsed Er:YAG Laser System
Common Name:	Er:YAG Pulsed Surgical 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. Technical Characteristics in Comparison to Predicate Device and Reference predicate Devices

LOTUS III Multi-Pulsed Er:YAG Laser System is substantially equivalent to the following legally marketed predicate device and Reference devices

	Primary Predicate Device	**Predicate Device**	**Predicate Device**	**Proposed Device**
510(K) Number	K083253	K093162	K143723	K182045

Manufacturer	Laseroptek Co., Ltd.	Stegne 7	Stegne 7	Laseroptek Co., Ltd.
Device Name	LOTUS II Pulsed Er:YAG Laser System	Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family	Fotona Dynamis Pro Family	LOTUS III Multi-Pulsed Er:YAG Laser System
Clearance Date:	15 May 2009	22 Jan 2010	9 April, 2015	Not available
Classification / Regulation	Class 2/ 21 CFR 878.4810	Class 2/ 21 CFR 878.4810	Class 2/ 21 CFR 878.4810	Class 2/ 21 CFR 878.4810
Product Code	GEX	GEX	GEX, ONG	GEX
Laser Type	Er:YAG	Er:YAG	Er:YAG	Er:YAG
Output mode	Pulsed	Pulsed	Pulsed	Pulsed
Wavelength	2940 nm	2940 nm	2940 nm	2940 nm
Pulse Characteristics:				
Pulse Duration (Pulse Width)	Short: 350 µs Long: 1 ms	50 – 1000 µs	MSP: 100 us SP: 300 us LP: 600 us VLP: 1000 us XLP: 1500 us SMOOTH mode: 250 ms V-SMOOTH mode with L-Runner; 100 ms, 200 ms, 300 ms, 400 ms and 500 ms TURBO	40 µs 200 µs 600 µs 1 ms 5 ms Six pulse mode, SM (200µs x 6 shots)
Pulse Energy (max)	Short: 1500 mJ Long: 1000 mJ	20 – 1500 mJ	30-3000 mJ	40 µs: 600 mJ 200 µs: 3000 mJ 600 µs: 900 mJ 1 ms: 1000 mJ 5 ms: 900 mJ SM: 18000 mJ
Average Power (max)	15 W	up to 20 W	up to 20 W	Up to 30 W
Spot size (mm)	Zoom: 1~7mm	-	Zoom: 1~7mm	Black: 1~7mm Blue: 15mm
Repetition Rate (Hz)	Up to 10 Hz	Up to 50 Hz	Up to 50 Hz	Up to 40 Hz
Fluence max	191 J/cm^2 (spot 1 mm)	-	382 J/cm^2 (spot 1 mm)	382 J/cm^2 (spot 1 mm) SM: 2292 J/cm^2 (spot 1 mm)

Aiming beam	Laser diode, 635 nm	Laser diode, 650 nm	Laser diode, 650 nm	Laser diode, 635 nm
Physical Characteristics:				
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Articulated Arm with Handpiece
Interface	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen
Activation	Via foot-switch	Via foot-switch	Via foot-switch	Via foot-switch
Cooling System	Internal Water to Air Heat Exchanger	-	Internal Water to Air Heat Exchanger	Internal Water to Air Heat Exchanger
System Dimensions (mm)	330(W) x 941.5mm(D) x 905.9mm(H)	-	-	298(W) x 819(L) x 936(H)
System Weight (kg)	100 kg	-	-	80 kg
Electrical Requirements	AC 220 V, 50/60 Hz	-	-	AC 220-230 V, 50/60 Hz

Reference Devices:

- Laseroptek Co. Ltd.'s PALLAS 308/311 Solid-State UV Laser System (K172639) *

  *This reference device is referred, of which cleaning method is the same to those of the PALLAS 308/311 Solid-State UV Laser System.

4. Device Description

Laseroptek Co. Ltd.'s LOTUS III Pulsed Er:YAG Laser System is an Erbrium:YAG laser with a wavelength of 2940 nm. A set of Er:YAG lasers is 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

The LOTUS III Multi-Pulsed Er:YAG Laser System is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

6. Performance Data

Non-clinical tests: Testing conducted on the LOTUS III Multi-Pulsed Er:YAG 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:

- LOTUS III 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.
- LOTUS III 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.
- LOTUS III 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 to FDA-recognized consensus standard IEC 60825-1: 2007. 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

LOTUS III Multi-Pulsed Er:YAG Laser System, from both a design and clinical perspective, uses similar or identical technology as the cited predicate devices and has the same intended uses. The general features of LOTUS III are similar to those of the predicates in particular as regards the classification IV laser, the equipment of the cooling system and the electrical specifications. Also, the predicate devices are equipped with a touch screen and activate via foot-switch.

Based upon the predicted overall performance characteristics for the LOTUS III Multi-Pulsed Er:YAG Laser System, Laseroptek Co. Ltd. believes that no significant differences exist in usage of its underlying technological principles between LOTUS III Multi-Pulsed Er:YAG Laser System and the cited predicate devices.

8. Conclusions

On the basis of the information provided in this Summary, Laseroptek Co., Ltd. Believes that LOTUS III Multi-Pulsed Er:YAG Laser System is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.