November 9, 2021

Convergent Laser Technologies
Jennifer Mok
Business Manager
1660 South Loop Road
Alameda, California 94502

Re: K211517
Trade/Device Name: Optica XT Thulium Fiber Laser and Accessories, also known as Optica XT, Optica XT Thulium Fiber Laser, Thulium Fiber Laser 1940 nm, Optica XT Thulium Fiber Laser 1940 nm, Optica XT 60 Thulium Fiber Laser 1940 nm, Optica XT Superpulse Thulium Fiber Laser 1940 nm, OptiLITE Laser Fibers and Accessories
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: September 14, 2021
Received: September 15, 2021

Dear Jennifer Mok:

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 and Part 809); 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,

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211517

Device Name
Optica XT Thulium Fiber Laser and Accessories, also known as Optica XT, Optica XT Thulium Fiber Laser, Thulium Fiber Laser 1940 nm, Optica XT Thulium Fiber Laser 1940 nm, Optica XT 60 Thulium Fiber Laser 1940 nm, Optica XT Superpulse Thulium Fiber Laser 1940 nm, OptiLITE Laser Fibers and Accessories

Indications for Use *(Describe)*

The Optica XT Thulium Fiber Laser and Accessories is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology
• Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
• Laser Resection of the Prostrate (LRP)
• Laser Enucleation of the Prostate (LEP)
• Laser Ablation of the Prostate (LAP)
• Transurethral Incision of the Prostate (TUIP)
• Condylomas
• Urethral strictures
• Lesions of external genitalia
• Bladder neck incisions (BNI)
• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy Indications
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones
• Endoscopic fragmentation of renal calculi
• Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:
• Appendectomy
• Polyps
• Biopsy
• Gall Bladder calculi
• Biliary/Bile duct calculi
• Ulcers
• Gastric ulcers
• Duodenal ulcers
• Non Bleeding Ulcers
• Pancreatitis
• Haemorrhoids
• Cholecystectomy
• Benign and Malignant Neoplasm
• Angiodysplasia
• Colorectal cancer

• Telangiectasias
• Telangiectasias of the Osler-Weber-Renu disease
• Vascular Malformation
• Gastritis
• Esophagitis
• Esophageal ulcers
• Varices
• Colitis
• Mallory-Weiss tear
• Gastric Erosions

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue.

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

I. General Information

Submitter/Manufacturer:	Xintec Corporation, dba, Convergent Laser Technologies 1660 South Loop Road Alameda, California 94502
Contact Person:	Jennifer Mok Regulatory Affairs & Quality Assurance Manager Direct: 510-280-7207 Fax: 510-832-1600
Date Prepared:	October 28, 2021

II. Device

Trade/Device Name:	Optica XT Thulium Fiber Laser and Accessories, also known as Optica XT, Optica XT Thulium Fiber Laser, Thulium Fiber Laser 1940 nm, Optica XT Thulium Fiber Laser 1940 nm, Optica XT 60 Thulium Fiber Laser 1940 nm, Optica XT Superpulse Thulium Fiber Laser 1940 nm, OptiLITE Laser Fibers and Accessories
Common or Usual Name	Surgical laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Regulatory Class:	II
Product Code:	GEX

III. Predicate Device

Manufacturer	Olympus Surgical Technologies America
Trade/Device Name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers and Accessories)
510(k) Number	K183647
Regulatory Class:	II
Product Code:	GEX

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

The Optica XT Thulium Fiber Laser is a thulium fiber laser emitting laser radiation at 1940 nm with a laser output power of 60 Watts. Laser activation is by footswitch. The overall weight of the laser is 95 lbs., and the size is 20" W x 24" L x 16" H. The Optica XT Thulium Fiber Laser has an electrical requirement of 100-240 VAC, 50/60 Hz. Laser energy is delivered to the target site using a fiber optic delivery system with diameters from 150-1000 micron.

V. Indications For Use

The Optica XT Thulium Fiber Laser and Accessories is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

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- Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
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- Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
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- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis

- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Haemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue.

VI. Comparison of Technological Characteristics

The Optica XT Thulium Fiber Laser and Accessories share the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is the same or similar to the predicate device. The design and function of the Optica XT Thulium Fiber Laser and Accessories are similar to the predicate device for the modes of operation and use.

Summary of the technological characteristics

Manufacturer	**Convergent Laser Technologies**	**Olympus Surgical Technologies America**	**Significant Differences**
Trade/Device Name	**Optica XT™ Thulium Fiber Laser and Accessories**	**SOLTIVE™ Laser Fibers, and Accessories**	N/A
510(k) Number	K211517	K183647	N/A
Product Code	GEX	GEX	Same
CFR Citation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Classification	Class II	Class II	Same
Generic/Common Name	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology	Same

Manufacturer	**Convergent Laser Technologies**	**Olympus Surgical Technologies America**	**Significant Differences**
Trade/Device Name	**Optica XT™ Thulium Fiber Laser and Accessories**	**SOLTIVE™ Laser Fibers, and Accessories**	N/A
Electrical Power	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Same
Size of Components (H x W x L)	16 x 20 x 24 inches	11.6 x 14.6 x 22 inches	Similar; components may be larger and needs a larger enclosure. No additional safety or efficacy concern as the component configuration is similar for a working laser.
Cooling	Air Cool	Air Cool	Same
Aiming Beam	532 nm, 3 mW	500-550 nm, power adjustable 0-5 mW	Similar, within range of the predicate device
Portability	Portable and can be placed on a medical cart	Portable and can be placed on a medical cart	Same
Fail Safe Control System	Master and Slave controller to verify fail-safe control. Master and slave control to verify laser actions for error warning and fail-safe conditions.	Software Fail Safe Control System	Similar; both devices' fail-safe control system passed the Electrical Safety Testing. No safety or efficacy concern have been identified.
Metal Enclosure	Aluminum enclosure	Aluminum enclosure	Same

Manufacturer	**Convergent Laser Technologies**	**Olympus Surgical Technologies America**	**Significant Differences**
Trade/Device Name	**Optica XT™ Thulium Fiber Laser and Accessories**	**SOLTIVE™ Laser Fibers, and Accessories**	N/A
Fiber Delivery Diameter	150 micron - 1000 micron multimode fiber optic delivery	150 micron - 1000 micron multimode fiber optic delivery	Same
Fiber Length	3 m	3 m	Same
Material of Fiber	Quartz, silicone protective coating	Quartz, silicone protective coating	Same
Control Method	Laser power monitor and verification	Laser power monitor and verification	Similar, both devices' software and energy monitoring system passed the Electrical Safety Testing. No safety or efficacy concern have been identified.
Laser Source	Thulium laser	Thulium laser	Same
Wavelength	1940 nm	1920 – 1960 nm	Within the range of the predicate.
Pulse Duration	100 µs	200 µs to 50 ms	Within the range of the predicate.
Frequency	5 to 1000 Hz	1 to 2,400 Hz	Within the range of the predicate.
Pulse Energy	0.1 to 6 J	0.025 to 6 J	Within the range of the predicate.
Range of laser power	60 Watts	60 Watts	Same

Manufacturer	**Convergent Laser Technologies**	**Olympus Surgical Technologies America**	**Significant Differences**
Trade/Device Name	**Optica XT™ Thulium Fiber Laser and Accessories**	**SOLTIVE™ Laser Fibers, and Accessories**	N/A
Weight	43 kg	40 kg	Similar, the device weighs more than the predicate device. Increased weight of the device does not add any concern or safety or efficacy.
Training Program	Yes	Yes	Same
Fail Safe Feature	Laser shuts down or go to STANDBY when detects failure or error	Laser shuts down or go to STANDBY when detects failure or error	Same
Electrical Safety Testing	AAMI/ANSI ES 60601-1:2005+A1 IEC 60601-1:2005+C1;C2;A1	AAMI/ANSI ES 60601-1:2005+A1 IEC 60601-1:2005	Same- AAMI/ANSI ES 60601-1:2005+A1 Similar, IEC 60601-1:2005, both systems meet IEC 60601-1 standards, the device was tested based on the current standard at the time of testing.
Electromagnetic Compatibility Testing	IEC 60601-1-2:2014, 4th Edition	IEC 60601-1-2:2007, 3rd Edition	Similar, both systems meet IEC 60601-1-2 standards, the device was tested based on the Edition current at the time of testing hence the Edition is not the same.

VII. Performance Data

Non-clinical performance data support safety of the device in accordance to the following standards:

- AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60825-1:2014, Edition 3.0, Safety of Laser Products – Part 1: Equipment Classification and Requirements
- IEC 60601-2-22:2012, Edition 3.1, Medical Electrical Equipment – Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
- IEC 60601-1-2:2014, Edition 4, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-1-6:2013, Edition 3.1, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 62304:2006, Ed. 1.0 + A1, Medical Device Software – Software Life Cycle Processes

Hardware and software verification and validation demonstrate that the Optica XT Thulium Fiber Laser and Accessories should perform as intended in the specified use conditions. Additionally, bench testing assessing the effect of bending stress on energy transmission in the optical fibers demonstrate comparable fiber performance.

Biocompatibility is in compliance with ISO 10993-1 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Optical fibers demonstrate compliance for the following biological endpoints:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity
- Hemocompatibility

This premarket submission for the Optica XT Thulium Fiber Laser and Accessories does not require clinical studies to support substantial equivalence.

VIII. Conclusions

Based on the nonclinical testing conducted, the Optica XT is the same or similar to its predicate device in regards to EMC and electrical safety. The differences in technological characteristics between the Optica XT and predicate device present no new questions of safety or effectiveness for the “indications for use” specified. Thus, the Optica XT is as safe, as effective, and performs as well as the legally marketed predicate device.