July 27, 2022

Dornier MedTech America, Inc.
John Hoffer
VP Quality, Regulatory, Clinical
1155 Roberts Blvd, Suite 100
Kennesaw, GA 30144

Re: K213252
Trade/Device Name: Dornier Thulio Laser
Regulation Number: 21 CFR§ 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 21, 2022
Received: June 21, 2022

Dear John Hoffer:

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,

Reginald K. Avery, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K213252

Device Name
Dornier Thulio Laser

Indications for Use *(Describe)*
The Dornier Thulio Laser is intended for minimally-invasive stone fragmentation, surgical tissue preparation such as cutting, ablation, coagulation and vaporization, in the following medical specialties:

Urology
a) Lithotripsy - Endoscopic fragmentation and pulverization of urethral, ureteral, bladder and renal stones
b) Benign Prostatic Hyperplasia (BPH)
c) Urethral Strictures
d) Bladder Neck Incision of the Prostate (BNI)
e) Superficial and invasive bladder, urethral and ureteral tumors

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

Dornier MedTech America's Thulio Laser

Submitter

Dornier MedTech America
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Kennesaw, GA 30144
Phone: 770-514-6163
Fax: 770-514-6291
Contact Person: John Hoffer

Date Prepared: July 27, 2022

Trade Name: Dornier Thulio Laser

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.

Regulation Number: 21 C.F.R. § 878.4810

Common or Usual Name: Surgical Powered Laser Instrument

Classification Panel: General & Plastic Surgery

Regulatory Class: Class II

Product Code: GEX

Predicate Device

Lumenis Pulse™ 100H/120H (K170121)

Reference Devices

Dornier Medilas H Solvo 35 Laser (K180350)
Dornier Medilas H140 (K161257)

Device Description

The Dornier Thulio is a compact, mobile, diode pumped Thulium, pulsed, single wavelength surgical laser with a wavelength of 2013 nm. The Dornier Thulio laser is comprised two functional components: (1) a laser console and (2) a dual pedal footswitch (wired or wireless).

The laser console emits laser radiation which is transmitted to the application site by a sterile fiber optic delivery system (fiber cable) with a SMA 905 connector. A graphic control panel regulates anddisplays the operating parameters, application modes, time functions, system status and messages to the user. The control panel consists of a display with integrated touch screen panel applications tocontrol the functions of the laser. Laser energy is transmitted by depressing a foot pedal. The foot pedals, both the wired and wireless models, are water-proof and explosion-proof.

The Dornier Thulio laser also has the same principles of operation as other currently available medical lasers (switch on the device, set energy, set frequency, set laser mode, connect the lightguide, prepare thefootswitch, activate the laser device).
The laser energy is transmitted via the use of a laser fiber connected to the Thulio laser. The fibers as noted below, are the same design as cleared in 510k's K984591, K121938, K152591 and K161771.

Core diameter [µm]	Packing unit [pcs]	Color code (at sleeve)	Item number
200*	3	white	K2016360
200**	3	white	K2016367
270slim*	3	white	K2016361
270slim*	3	white	K2016368
270*	3	blue	K2016362
400*	3	yellow	K2016363
400*	3	yellow	K2016364
600*	3	green	K2016365
1000*	3	red	K2016366

*) SingleFlex Performance
**) GentleFlex Performance

Indications for Use

The indications for use for the subject device is:
The Dornier Thulio Laser is intended for minimally-invasive stone fragmentation, surgical tissue preparation such as cutting, ablation, coagulation and vaporization in the following medical specialties:

Urology
a) Lithotripsy - Endoscopic fragmentation and pulverization of urethral, ureteral, bladder and renal stones
b) Benign Prostatic Hyperplasia (BPH)
c) Urethral Strictures
d) Bladder Neck Incision of the Prostate (BNI)
e) Superficial and invasive bladder, urethral and ureteral tumors

The indications for use for the predicate device is:
The Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories (VersaPulse PowerSuite, Lumenis Pulse 30H, Lumenis Pulse 50H, Lumenis Pulse 60H, Lumenis Pulse 100H and Lumenis Pulse 120H) are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery.

The Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories are indicated for use in the performance of specific surgical applications as follows:

Urology
- Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), holmium laser resection of the prostate (HoLRP), hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy (BPH)

- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
  - bladder;
  - superficial and invasive bladder, urethral and ureteral tumors;
  - condylomas;
  - lesions of external genitalia;
  - ureteral and penile hemangioma;
  - ureteral strictures;
  - bladder neck obstructions
- Urinary Lithotripsy including:
  - endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones;
  - treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including:
  - meniscectomy;
  - plica removal;
  - ligament and tendon release;
  - contouring and sculpting of articular surfaces;
  - debridement of inflamed synovial tissue (synovectomy);
  - loose body debridement;
  - chondromalacia and tears;
  - lateral retinecular release;
  - capsulectomy in the knee;
  - chondroplasty in the knee;
  - chondrornalacia ablation.
- Discectorny including:
  - percutaneous vaporization of the L4-5 and LS-SI lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

General Surgery

- Open, laparoscopic, and endoscopic general surgery (vaporization, ablation, incision, and coagulation of soft tissue) including:
  - cholecystectomy;
  - lysis of adhesions;
  - appendectomy;
  - biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon;
  - skin incision;
  - tissue dissection;
  - excision of external tumors and lesions;
  - complete or partial resection of internal organs, tumors and lesions;
  - mastectomy;
  - hepatectomy;
  - pancreatectomy;
  - splenectomy;
  - thyroidectomy;
  - parathyroidectomy;
  - herniorrhaphy;
  - tonsillectomy;
  - lymphadenectomy;
  - partial nephrectomy;
  - opilonidal cystectomy;
  - resection of lipoma;
  - debridement of decubitus ulcer;
  - hemorrhoids;

- debridement of statis ulcer;
- biopsy.

ENT Surgery

- Endoscopic endonasal/ sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
  - partial turbinectomy;
  - ethmoidectomy;
  - polypectomy;
  - maxillary antrostomy;
  - frontal sinusotomy;
  - sphenoidotomy;
  - dacryocystorhinostomy (DCR);
  - functional endoscopic sinus surgery (FESS).

Gynecological Surgery

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

Gastroenterology Surgery

- Open and endoscopic gastroenterology surgery (ablation, vaporization, incision, excision, resection, coagulation and hemostasis, including:
  - gall bladder calculi;
  - Biliary /bile duct calculi;
  - benign and malignant neoplasm;
  - polyps;
  - colitis;
  - ulcers;
  - angiodysplasia;
  - hemorrhoids;
  - varices;
  - esophagitis;
  - esophageal ulcer;
  - Mallory-Weiss tear;
  - gastric ulcer;
  - duodenal ulcer;
  - non-bleeding ulcer;
  - gastric erosions;
  - colorectal cancer;
  - gastritis;
  - bleeding tumors;
  - pancreatitis;
  - vascular malformations;
  - telangiectasia;
  - telangiectasia of the Osler-Weber-Renu disease.

Pulmonary Surgery

- Open and endoscopic pulmonary surgery (cutting, ablation, vaporization, incision, excision and coagulation of soft tissue.

Dermatology and plastic surgery

- Incision, excision, resection, ablation, coagulation, hemostasis and vaporization of soft, mucosal, fatty and cartilaginous tissues, in therapeutic plastic, dermatologic and aesthetic surgical procedures, including:
  - scars;
  - tattoo removal;
  - vascular lesions;

- port wine stains;
- hemangioma;
- telangiectasia of the face and leg;
- rosacea;
- corns;
- papilloma;
- basal cell carcinomas;
- lesions of skin and subcutaneous tissue;
- plantar warts;
- periungual and subungual warts;
- debridement of decubitus ulcer;
- skin tag vaporization.

Comparison of indications for use statements

With respect to urological uses, the IFU statement of the subject device is very similar to that of the predicate. Both devices have similar general purpose laser usages (i.e., cutting, ablation, coagulation and vaporization), and same specific procedures (laser lithotripsy of urinary tract stones, BPH, urethral strictures, bladder neck incision, and excision of bladder, urethral and ureteral tumors). The subject and predicate device have the same intended use.

Summary of Technological Characteristics

The Thulio laser is substantially equivalent to the Lumenis Pulse 100H/120H (K170121). Both the subject device and the predicate device are single wavelength, solid state lasers intended for use in urological and/or gastroenterological surgical procedures. They are controlled by proprietary software and the units are operated by a footswitch. Further, both units have a similar user interface, a graphic control panel regulates and displays the operating parameters, application modes, time functions, system status and messages to the user. Both the Thulio and the predicate device are solid state lasers that emit a pulsed laser wave with the active laser medium being a YAG-crystal, which is doped with thulium (Tm: YAG) for the Thulio laser and holmium (Ho:YAG) for the predicate device. The primary technological difference between the Thulio laser and the predicate device is the wavelength of the two lasers. Specifically, the Thulio laser operates at 2013 nm while the predicate device operates at 2100 nm. However, this difference does not raise new or different questions of safety or effectiveness as both laser devices are pulsed solid-state lasers designed to perform the same functions, namely cutting, ablation, coagulation and vaporization in urological and gastroenterological procedures. The basic operating principles of the Thulio and the predicate device are also directly comparable tothe predicate device and other medical lasers currently marketed in the U.S. In addition, performance testing has demonstrated that the subject device is as safe and effective as the predicate device.

A table comparing the key features of the subject and predicate devices is provided below.

	Dornier Thulio Laser	**The LUMENIS PULSE™ 100H/120H Laser**
Type of Laser	Solid-state lasers. Uses YAG crystal doped with Thulium	Solid-state laser. Uses Holmium-doped YAG crystal
Wavelength	2013 nm	2100 nm
Output Power	100 W	100 W (100H) 120 W (120H)
Pulse Energy	0.1-2.5J	0.2-3.5J (100H) 0.2-6J (120H)

Pulse Duration	150 – 1000 µs	150-600 us (100H) < 1300us 120H
Pulse Frequency	5 – 300 Hz	5-53 Hz (100H) 5-80 Hz (120H)
Pre set Mode settings	Yes	Yes
Minimum Fiber Diameter	Compatible with light guides with core diameter: between 200µm and 1000µm	Compatible with light guides with core diameter: between 200µm and 1000µm
Aiming Beam	Green wavelength, 520 nm	Green wavelength, 532 nm
RFID Capable	Yes	Yes

Non-Clinical Performance Data

The subject device was evaluated according to the following recognized consensus standards and FDA Guidance documents:

- IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance

- IEC 60601-1-2:2014, ed 4, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.

- IEC 60601-2-22: 2012, ed 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 60825-1:2014, ed 3.0, Safety of laser products - Part 1: Equipment classification and requirements

- IEC60601-1-6:2013, ed 3.1, Medical Electrical Equipment Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

- Software verification and validation testing in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Non-clinical bench testing was performed as well as a detailed literature search to demonstrate he Thulio's equivalence to the predicate and similar devices in regard to their clinical use in urological procedures. The two primary clinical functions tested and reviewed were lithotripsy (dusting performance and retropulsion) and cutting/coagulation functions.

For lithotripsy, the comparison between Dornier Thulio and the Medilas H Solvo 35 Ho:YAG device (reference device) demonstrated that both devices produced similar pressure in almost all investigated settings. The in-vitro experiments demonstrated that both devices have a comparable risk profile for laser lithotripsy in terms of the pressure produced. The study concluded that the Dornier Thulio's dusting performance proved to be comparable to that of the Medilas H Solvo 35 Ho:YAG laser device (reference device) at similar settings. In terms of fragmentation performance, the study concluded that the fragmentation efficiency of Ho:YAG was similar to the Dornier Thulio subject device.

A study on the laser-induced retropulsion force was performed using the Dornier Thulio was compared to the reference Ho:YAG laser Medilas H Solvo 35. With the same laser settings, both laser devices gave comparable values with a slight tendency towards lower retropulsion forces with the Dornier Thulio.

An in-vitro study assessing the tissue cutting and coagulation performance of the Thulio compared to a high power Ho:YAG laser (Dornier Medilas H140), low-power Ho:YAG laser (Dornier Medilas H Solvo 35 Laser). The results of the study concluded that the enucleation/coagulation performance of the Dornier Thulio was rated comparable to that of the lasers (both high and low power) used in the study.

The results of the non-clinical performance testing demonstrated that the device is as safe and effective for its intended use as the predicate.

Conclusion

The Thulio laser and the predicate devices have the same intended use and similar indications, technological characteristics and principles of operation. The minor technological differences between the Thulio laser and its predicates do not present different questions of safety or effectiveness. Furthermore, performance testing has demonstrated that the subject device is as safe and effective as the predicate device. Thus, the Thulio laser is substantially equivalent to the predicate device.