May 22, 2017

Lumenis Ltd.
Yehudit Kraizer
Regulatory Affairs Director
Yokneam Industrial Park, 6 Hakidma Street, PO Box 240
Yokneam, 2069204, Israel

Re: K170121


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: May 7, 2017
Received: May 10, 2017

Dear Yehudit Kraizer:

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" (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 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,

Jennifer R. Stevenson -S

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
Indications for Use

Device Name

Indications for Use (Describe)
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 retinacular release;
  - capsulectomy in the knee;
  - chondroplasty in the knee;
  - chondromalacia ablation.
- Discectomy 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;
  - pilonidal cystectomy;
  - resection of lipoma;
  - debridement of decubitus ulcer;
  - hemorrhoids;
  - debridement of stasis 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-Rendu 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.
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510(k) SUMMARY

Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories

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Date Prepared: 09 January, 2017


Classification Name: Powered laser surgical instrument
Product Code: GEX

Device Class: Class II

Regulation Number: 21 CFR 878.4810
Panel: General & Plastic Surgery

Predicate Device: Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories—Lumenis Pulse 120H, cleared under K140388.
**Intended Use/ Indications for Use:**
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.

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- 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;
- chondromalacia ablation.

- Discectomy 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;
  - heptatectomy;
  - pancreatectomy;
  - splenectomy;
  - thyroidectomy;
  - parathyroidectomy;
  - herniorrhaphy;
  - tonsillectomy;
  - lymphadenectomy;
  - partial nephrectomy;
  - epilonidal 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 subungal warts;
- debridement of decubitus ulcer;
- skin tag vaporization.

**Device Description:**

The Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories (also referred to as 'Lumenis Family of Holmium Surgical Lasers'), subject of this submission, is a family of single wavelength holmium (Ho:YAG) lasers manufactured by Lumenis Ltd. The family is composed of two main series; the VersaPulse PowerSuite series (VPPS) which includes the VersaPulse PowerSuite 20W, VersaPulse PowerSuite 30W, VersaPulse PowerSuite 45W, VersaPulse PowerSuite 60W, VersaPulse PowerSuite 80W and VersaPulse PowerSuite 100W, cleared under K011703, together with the VersaPulse P20 cleared under K100228, and the modern Lumenis Pulse series which includes the recently cleared Lumenis Pulse 120H system (K140388) and further expanded with the addition of the Lumenis Pulse 30H, Lumenis Pulse 50H, Lumenis Pulse 60H and Lumenis Pulse 100H, subjects of this submission.

The modifications to the subject Lumenis Family of Holmium Surgical Lasers include addition of modernized family members as well as updates to existing systems. Mainly, the subject additional devices are basically similar to the previously cleared Lumenis Pulse 120H (LP120H, recently cleared under K140388). The modified Lumenis Pulse 30H, Lumenis Pulse 50H, Lumenis Pulse 60H and Lumenis Pulse 100H systems rely on the same fundamental underlying technology of the cited predicate systems with the laser power outputs similar to the previously cleared configurations of the VersaPulse PowerSuite series cleared under K011703. The subject device modifications involve both hardware (HW) and software (SW) elements, whereas the functional capabilities of the laser systems remain unaltered in both the modified and cleared systems. The Lumenis Lumenis Pulse 60H and 120H are provided with the Moses Mode, based on the well-known Moses Effect, which limits the attenuation of holmium laser energy in the liquid environment, thus reducing dependency of the fiber positioning (i.e. distance) in respect to the target tissue. All other characteristics of the laser emission are maintained identical as in the cleared Regular Mode.
All of the modified Lumenis Family of Holmium Surgical Lasers are solid state Single Wavelength (Holmium) surgical laser, comprised of the following functional components:

- Laser Console
- Dual or single pedal Footswitch
- Variety of Fiber Optic Delivery Devices (fibers) and accessories
- An integrated suction pump and accessories (Lumenis Pulse 120H and Lumenis Pulse 60H)

The systems are operated and controlled via proprietary SW. The SW comprises embedded SW in the main and peripheral processors, and Graphical User Interface (GUI) application running on a Personnel Computer (PC).

**Substantial Equivalence:**

The intended use and indications for use of the Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories are identical to the intended use and indications for use of its predicate Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories, Lumenis Pulse 120H. In addition, the same technological characteristics and principles of operation apply for both families. 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) includes additional family members and is thus an expansion of the cleared family of Holmium Lasers, as well as additional modifications incorporated in certain family members. Indeed, the new introduced members share the same fundamental technology as the cleared systems. As in the cleared systems the new members identically enable control of the pulse duration and in addition the subject LP60H and LP120H include an enhancement of the previously described “Moses effect” (i.e. Moses Mode). This modification however, does not raise different questions of safety and efficacy, rather facilitates the physician by reducing the dependency of the fiber distance from the target tissue.

Performance testing was conducted in order to demonstrate the specifications and performance of the Lumenis Family of Holmium Surgical Lasers and to verify that no different questions of safety and effectiveness have been raised due to the modifications introduction. Test results indicated that the subject Lumenis Family of Holmium Surgical Lasers performs in accordance with its requirements and specifications, in similarity to its predicate family.
Performance Testing:

- Risk analysis activities, in compliance with the requirements of ISO 14971: 2007 Medical devices - Application of Risk Management to Medical Devices
- Electrical and laser safety and electromagnetic compatibility tests, in compliance with:
- Software verification and validations, in compliance with FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (issue on 2005). The tests verified that the subject Lumenis Holmium Surgical Lasers performs according to its specifications.
- Sterilization validation in compliance with and ISO 11135 2nd ed.: 2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ex-vivo and the in-vivo set ups demonstrate comparable tissue response and in particular similar thermally coagulated zones, supporting that the Moses Mode does not raise any new issues of safety and efficacy as compared to the Regular Mode.

Summary

In summary, it is Lumenis belief that the Lumenis Family of Holmium Surgical Lasers is as safe and effective for its intended use as its predicate and is substantially equivalent to its predicate family without raising any different safety and/or effectiveness issues.