

AUG 29 2001

Attachment 11

K 011703

510(k) Summary Statement for the Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

I. General Information

Submitter: Lumenis  
2400 Condensa Street  
Santa Clara, California, U. S. A.  
95051-0901

Contact Person: Lisa G. McGrath

Summary Preparation Date: May 30, 2001

II. Names

Device Names: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (K990947);
- Trimedyn Holmium Laser Systems (model 1210, model 1010-VHP, and model 1500-A) (K002308)
- Dornier Medilas H/2 Laser System (K984591)
- Convergent Odyssey 30 Laser System (K951910).

IV. Product Description

The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers that are the subject of this Premarket Notification 510(k) submission are comprised of the following functional components:

- a laser console;
- control and display panel;

**Summary of Safety and Effectiveness,  
Page 2**

- a fiber port for delivery systems;
- system microprocessor control electronics;
- a covered footswitch or handswitch;
- operating software;
- an optional remote control unit;
- a variety of fiber optic delivery devices with accessories.

The Lumenis delivery devices that are the subject of this Premarket Notification 510(k) submission are comprised of all or some (depending on the product configuration) of the following functional components:

- laser connector;
- handpiece;
- probe tube;
- probe tip;
- fiber optic cable.

**V. Indications for Use**

The modified and the currently marketed VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers 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:

- Ho:YAG - urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery ; gastroenterology surgery; dermatology and plastic surgery and general surgery.
- Nd:YAG - urology; general surgery; gastroenterology; thoracic & pulmonary surgery; E.N.T. surgery; podiatry; orthopaedics; dermatology and plastic surgery and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy.

The modified and the currently marketed VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers are indicated for use in the performance of specific surgical applications in urology, urinary lithotripsy, arthroscopy/orthopaedics, discectomy, E.N.T. surgery, gynecological surgery/gynecology, general surgery, gastroenterology, thoracic and pulmonary surgery, dermatology and plastic surgery, podiatry, and limited indications in neurosurgery, ophthalmology, and lumbar discectomy as follows:

Summary of Safety and Effectiveness,

Page 3

Ho:YAG – 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.

Nd:YAG - Urology

- Urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including:
  - removal of superficial bladder tumors;
  - removal of invasive bladder carcinoma;
  - removal of benign or malignant lesions of the external genitalia, including condylomas;
  - treatment of urethral strictures;
  - treatment of vascularities of the bladder wall;
  - prostatectomy.

Ho:YAG – Arthroscopy

- Arthroscopy/orthopaedic surgery (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;

Summary of Safety and Effectiveness,  
Page 4

- 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 L5-S1 lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

Nd:YAG - Orthopaedic Surgery

- Arthroscopy (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

Knee

- capsulectomy in the knee;
- chondroplasty in the knee;
- plica removal in the knee;
- lateral ligament release in the knee;
- meniscectomy in the knee;
- synovectomy in the knee;
- osteoarthritic lesion removal in the knee;

Shoulder

- coracoacromial release in the shoulder;
- debridement of scar tissue in the shoulder;
- adhesive capsule release in the shoulder;
- labral tear repair in the shoulder;
- synovectomy in the shoulder.

- Discectomy:  
limited to open, percutaneous and arthroscopic vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine in patients with:
  - unilateral leg pain greater than back pain;
  - paresthetic discomfort in a specific dermatomal distribution;
  - positive straight leg raising test and/or positive bowstring sign;
  - possible neurologic finding including wasting, weakness, sensory alteration and reflex alteration;
  - no improvement after at least 6 weeks of conservative therapy;

Summary of Safety and Effectiveness,  
Page 5

- positive CT or MRI showing a subligamentous herniation at the location consistent with clinical findings.

Ho:YAG - 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.

Nd:YAG - General Surgery

- Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - cholecystectomy;
  - mastectomy;
  - hepatectomy;
  - pancreatectomy;
  - splenectomy;
  - hemorrhoidectomy;

**Summary of Safety and Effectiveness,  
Page 6**

- thyroidectomy;
- parathyroidectomy;
- herniorrhaphy;
- tonsillectomy;
- appendectomy;
- lymphadenectomy;
- partial nephrectomy;
- pilonidal cystectomy;
- resection of lipoma;
- pelvic adhesiolysis;
- removal of lesions;
- removal of polyps;
- removal of tumors;
- tumor biopsy;
- debridement of decubitus ulcers.

Ho:YAG – E.N.T. 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).

Nd:YAG – E.N.T. Surgery

- Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues;
  - tonsillectomy;
  - adenoidectomy.

Ho:YAG - Gynecological Surgery

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

Nd:YAG - Gynecological Surgery

- Gynecological surgery limited to:

Summary of Safety and Effectiveness,  
Page 7

- treatment of menorrhagia by the photocoagulation, vaporization, or ablation, of the endometrial lining of the uterus under direct hysteroscopic visualization;
- intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation, and/or vessel coagulation;
- intra-abdominal treatment of endometriosis and/or peritoneal adhesions with laser contact tips;
- soft tissue excisional procedures such as excisional conization of the cervix.

Ho:YAG – 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;
  - telangiectasias;
  - telangiectasias of the Osler-Weber-Renu disease.

Nd:YAG - Gastroenterology Surgery

- Gastroenterology surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - partial removal of neoplastic tissue in the management of esophageal obstruction for symptomatic relief of dysphagia;

Summary of Safety and Effectiveness,  
Page 8

- gastrointestinal hemostasis including, varicies, esophagitis, esophageal ulcer, Mallory-Wiess tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, and gastric erosions;
- gastrointestinal tissue ablation of benign and malignant neoplasm, hemorrhoids and polyps.

Ho:YAG - Pulmonary Surgery

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

Nd:YAG - Thoracic and Pulmonary Surgery

- Thoracic and pulmonary surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of:
  - laryngeal lesions;
  - airway obstructions including carcinoma;
  - polyps and granulomas;
  - palliation of obstructing carcinomas of the tracheobronchial tree.

Ho:YAG – 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;
  - papillomas;
  - basal cell carcinomas;
  - lesions of skin and subcutaneous tissue;
  - plantar warts;
  - periungual and subungual warts;
  - debridement of decubitus ulcer;
  - skin tag vaporization.

Nd:YAG - Dermatology and Plastic Surgery

- Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - lesions of skin and subcutaneous tissue;
  - telangiectasia;
  - port wine lesions;

Summary of Safety and Effectiveness,  
Page 9

- spider veins;
- hemangiomas;
- plantar warts;
- periungual and subungual warts;
- removal of tattoos;
- debridement of decubitus ulcer;
- treatment of keloids.

Nd:YAG - Podiatry

- Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - matrixectomy;
  - plantar warts;
  - neuromas;
  - periungual and subungual warts;
  - radical nail excision.

Nd:YAG - Neurosurgery

- Neurosurgery limited to:
  - hemostasis in neurosurgery procedures such as excision of brain lesions, spinal cord lesions, cranial nerves, peripheral nerves, and pituitary glands.

Nd:YAG - Ophthalmology

- Ophthalmology limited to:
  - post-vitreotomy photocoagulation.

**V. Rationale for Substantial Equivalence**

The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories share the same intended use, indications for use, similar design features, functional features, and therefore are substantially equivalent to the VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories.

In addition, the Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers are substantially equivalent in terms of indications for use to the Trimedyne Holmium Laser Systems (model 1210, model 1010-VHP, and model 1500-A) (K002308), the Dornier Medilas H/2 Laser System (K984591) and the Convergent Odyssey 30 Laser System (K951910).

**Summary of Safety and Effectiveness,  
Page 10**

The Lumenis delivery devices are substantially equivalent to the previously cleared delivery devices in K990947.

**VII. Safety and Effectiveness Information**

Safety and effectiveness information was provided to demonstrate that the Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories are safe and effective, when indicated for use for general and specific applications in the medical specialties of urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery, gastroenterology surgery, dermatology and plastic surgery and general surgery; for Ho:YAG and urology; general surgery; gastroenterology; thoracic and pulmonary surgery; E.N.T. surgery; podiatry; orthopaedics; and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy for Nd:YAG.

**VIII. Conclusion**

The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories were found to be substantially equivalent to similar currently marketed and predicate surgical lasers, delivery devices and accessories.

The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories share the same intended use, indications for use, similar design features, and similar functional features as the currently marketed VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories. The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories is also substantially equivalent in terms of indications for use to the Trimedyne Holmium Laser Systems (model 1210, model 1010-VHP, and model 1500-A) (K002308), the Dornier Medilas H/2 Laser System (K984591) and the Convergent Odyssey 30 Laser System (K951910).



AUG 29 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lisa G. McGrath  
Senior Regulatory Affairs Associate  
Lumenis  
2400 Condensa Street  
Santa Clara, California 95051

Re: K011703

Trade/Device Name: Modified Lumenis VersaPulse® PowerSuite®™ Holmium (Ho:YAG)  
and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers & Delivery  
Devices with Accessories

Regulation Number: 878.4810

Regulatory Class: II

Product Code: GEX

Dated: May 30, 2001

Received: June 1, 2001

Dear Ms. McGrath:

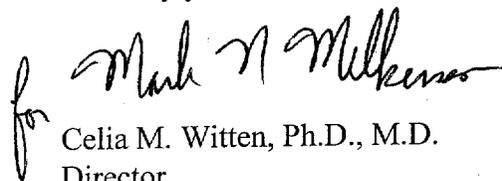
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Milken

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Attachment 3  
Indications For Use Statement

510(k) Number (if Known): K011703

Device Name: Modified Lumenis VersaPulse® PowerSuite™ Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers & Delivery Devices with Accessories

**Indications For Use:**

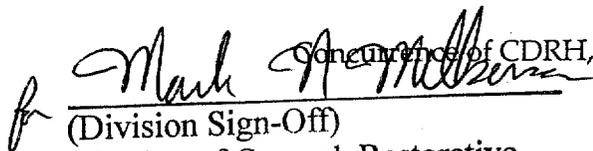
The modified and the currently marketed VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with accessories are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

- Ho:YAG - urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery.
- Nd:YAG - urology; general surgery; gastroenterology; thoracic & pulmonary surgery; E.N.T. surgery; podiatry; orthopaedics; dermatology and plastic surgery and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy.

The modified and the currently marketed VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with accessories are indicated for use in the performance of specific surgical applications in urology, urinary lithotripsy, arthroscopy/orthopaedics, discectomy, E.N.T. surgery, gynecological surgery/gynecology, general surgery, gastroenterology, thoracic and pulmonary surgery, dermatology and plastic surgery, podiatry, and limited indications in neurosurgery and ophthalmology as follows:

\*\*\* Indications For Use Continued on Next Page (9 pages total) \*\*\*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

  
\_\_\_\_\_  
Concurrent Director, Office of Device Evaluation (ODE)  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K011703  
Prescription Use  Or Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Attachment 3 – Continued (page 2 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications For Use:

Ho:YAG – 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.

Nd:YAG - Urology

- Urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including:
  - removal of superficial bladder tumors;
  - removal of invasive bladder carcinoma;
  - removal of benign or malignant lesions of the external genitalia, including condylomas;
  - treatment of urethral strictures;
  - treatment of vascularities of the bladder wall;
  - prostatectomy.

  
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(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

Attachment 3- Continued (page 3 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications for Use:

Ho:YAG - 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 L5-S1 lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

Nd:YAG - Orthopaedic Surgery

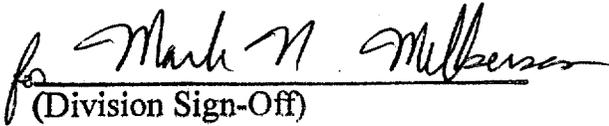
- Arthroscopy (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

Knee

- capsulectomy in the knee;
- chondroplasty in the knee;
- plica removal in the knee;
- lateral ligament release in the knee;
- meniscectomy in the knee;
- synovectomy in the knee;
- osteoarthritic lesion removal in the knee;

Shoulder

- coracoacromial release in the shoulder;
- debridement of scar tissue in the shoulder;

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

Attachment 3 – Continued (page 4 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications For Use:

Nd:YAG - Orthopaedic Surgery - Continued

- adhesive capsule release in the shoulder;
- labral tear repair in the shoulder;
- synovectomy in the shoulder.
  
- Discectomy:  
limited to open, percutaneous and arthroscopic vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine in patients with:
  - unilateral leg pain greater than back pain;
  - paresthetic discomfort in a specific dermatomal distribution;
  - positive straight leg raising test and/or positive bowstring sign;
  - possible neurologic finding including wasting, weakness, sensory alteration and reflex alteration;
  - no improvement after at least 6 weeks of conservative therapy;
  - positive CT or MRI showing a subligamentous herniation at the location consistent with clinical findings.

Ho:YAG - 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;

*for Mark A. Mulken*  
\_\_\_\_\_  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K011703

Attachment 3 – Continued (page 5 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications For Use:

Ho:YAG - General Surgery - Continued

- o herniorrhaphy;
- o tonsillectomy;
- o lymphadenectomy;
- o partial nephrectomy;
- o pilonidal cystectomy;
- o resection of lipoma;
- o debridement of decubitus ulcer;
- o hemorrhoids;
- o debridement of stasis ulcer;
- o biopsy.

Nd:YAG - General Surgery

- Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - o cholecystectomy;
  - o mastectomy;
  - o hepatectomy;
  - o pancreatectomy;
  - o splenectomy;
  - o hemorrhoidectomy;
  - o thyroidectomy;
  - o parathyroidectomy;
  - o herniorrhaphy;
  - o tonsillectomy;
  - o appendectomy;
  - o lymphadenectomy;
  - o partial nephrectomy;
  - o pilonidal cystectomy;
  - o resection of lipoma;
  - o pelvic adhesiolysis;
  - o removal of lesions;
  - o removal of polyps;
  - o removal of tumors;
  - o tumor biopsy;
  - o debridement of decubitus ulcers.

*for Mark N. Melberson*

(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K 011703

Attachment 3 – Continued (page 6 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications For Use:

Ho:YAG – E.N.T. 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)

*for Mark N. Mulberry*

(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

K011703

510(k) Number \_\_\_\_\_

Nd:YAG – E.N.T. Surgery

- Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues;
  - tonsillectomy;
  - adenoidectomy.

Ho:YAG - Gynecological Surgery

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

Nd:YAG - Gynecological Surgery

- Gynecological surgery limited to:
  - treatment of menorrhagia by the photocoagulation, vaporization, or ablation, of the endometrial lining of the uterus under direct hysteroscopic visualization;
  - intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation, and/or vessel coagulation;
  - intra-abdominal treatment of endometriosis and/or peritoneal adhesions with laser contact tips;
  - soft tissue excisional procedures such as excisional conization of the cervix.

Attachment 3 – Continued (page 7 of 9)  
Indications For Use Statement

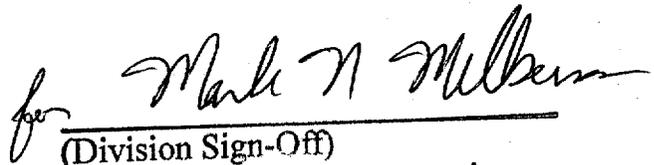
510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

**Indications For Use:**

Ho:YAG – 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;
  - telangiectasias;
  - telangiectasias of the Osler-Weber-Renu disease.



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Division of General, Restorative  
and Neurological Devices

510(k) Number \_\_\_\_\_

KO11703

Nd:YAG - Gastroenterology Surgery

- Gastroenterology surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - partial removal of neoplastic tissue in the management of esophageal obstruction for symptomatic relief of dysphagia;
  - gastrointestinal hemostasis including, varicies, esophagitis, esophageal ulcer, Mallory-Wiess tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, and gastric erosions;
  - gastrointestinal tissue ablation of benign and malignant neoplasm, hemorrhoids and polyps.

Attachment 3 – Continued (page 8 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications For Use:

Ho:YAG - Pulmonary Surgery

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

Nd:YAG - Thoracic and Pulmonary Surgery

- Thoracic and pulmonary surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of:
  - laryngeal lesions;
  - airway obstructions including carcinoma;
  - polyps and granulomas;
  - palliation of obstructing carcinomas of the tracheobronchial tree.

Ho:YAG – 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;
  - papillomas;
  - basal cell carcinomas;
  - lesions of skin and subcutaneous tissue;
  - plantar warts;
  - periungual and subungual warts;
  - debridement of decubitus ulcer;
  - skin tag vaporization.

*for Mark N. Milburn*  
\_\_\_\_\_  
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Division of General, Restorative  
and Neurological Devices

510(k) Number K011703

Attachment 3 – Continued (page 9 of 9)  
Indications For Use Statement

510(k) Number (if Known): \_\_\_\_\_

Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

Indications For Use:

Nd:YAG - Dermatology and Plastic Surgery

- Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - lesions of skin and subcutaneous tissue;
  - telangiectasia;
  - port wine lesions;
  - spider veins;
  - hemangiomas;
  - plantar warts;
  - periungual and subungual warts;
  - removal of tattoos;
  - debridement of decubitus ulcer;
  - treatment of keloids.

*for Mark A. Miller*  
\_\_\_\_\_  
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and Neurological Devices

510(k) Number K011703

Nd:YAG - Podiatry

- Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - matrixectomy;
  - plantar warts;
  - neuromas;
  - periungual and subungual warts;
  - radical nail excision.

Nd:YAG - Neurosurgery

- Neurosurgery limited to:
  - hemostasis in neurosurgery procedures such as excision of brain lesions, spinal cord lesions, cranial nerves, peripheral nerves, and pituitary glands.

Nd:YAG - Ophthalmology

- Ophthalmology limited to:
  - post-vitreotomy photocoagulation.

\*\*\* (page 9 of 9) \*\*\*