

4/24/97

K 990947

Attachment 14

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

I. General Information

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

Contact Person: Michelle P. Deeton

Summary Preparation Date: March 19, 1999

II. Names

Device Names: Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and compatible fiber optic laser delivery devices with accessories (sterilization trays)

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

III. Predicate Devices

- Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (K980685, K933318);
- Coherent VersaPulse Single Wavelength (Ho:YAG) and Coherent Ho:YAG Surgical Lasers (K932981, K923575, K914991, K914136, K910037, K902990, K895518);
- Coherent SlimLine Single Lumen Aspiration Needle Kit - Sterilization Tray (K960413);
- Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers (K974789);
- TTI Medical Accu-Beam Fiber Optic Handpiece (K952006).

IV. Product Description

The Modified Coherent VersaPulse Select Single Wavelength (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;

- 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 (described below).

The Coherent 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.

The Coherent Accessories (sterilization trays) are comprised of the following functional components:

- tray lid and tray bottom;
- latches;
- instrument supports.

V. Indications for Use

The Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (and their delivery accessories) are intended for use in surgical procedures involving open, laproscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

- Ho:YAG - urology; urinary lithotripsy; arthroscopy; discectomy; endonasal surgery; gynecological surgical; and general surgery; and
- Nd:YAG - urology; general surgery; gastroenterology; thoracic and pulmonary surgery; ENT surgery; podiatry; orthopaedics; and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy.

The modified and the currently marketed Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (and the delivery accessories that are used with them to deliver laser energy) are indicated for use in the performance of specific surgical applications in urology, urinary lithotripsy, arthroscopy/orthopaedics, discectomy, endonasal surgery/ENT surgery, gynecological surgery/gynecology, general surgery, gastroenterology, thoracic and pulmonary surgery, dermatology and plastic surgery, podiatry, and limited indications in gynecology, neurosurgery, ophthalmology, and lumbar discectomy as follows:

Ho:YAG - Urology

- Endoscopic holmium laser resection of the prostate (HoLRP) with the VersaPulse Select Ho:YAG and Ho:YAG/Nd:YAG Surgical Lasers for treatment of benign prostatic hypertrophy (BPH).

Ho:YAG - Urology - Continued

- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
 - bladder;
 - urethral and ureteral tumors;
 - condylomas;
 - lesions of external genitalia;
 - urethral and penile hemangioma;
 - urethral strictures;
 - bladder neck obstructions.
- Urinary Lithotripsy including:
 - endoscopic fragmentation of urinary calculi in the ureter or ureteropelvic junction;
 - 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 - Arthroscopic Surgery/Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft tissue) in various 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.
- Discectomy including:
 - percutaneous vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine;
 - open and arthroscopic spine procedures.

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;
 - 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;
 - removal of benign and malignant lesions;
 - biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon.

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;
 - 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 - Endonasal Surgery

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

Nd:YAG - Ear, Nose and Throat (ENT) 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.

Nd:YAG - Gastroenterologic Surgery

- Gastroenterologic 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.

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.

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.

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.

VI. Rationale for Substantial Equivalence

The Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the Coherent VersaPulse Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (K980685, K933318) and the Coherent VersaPulse Single Wavelength (Ho:YAG) and Coherent Ho:YAG Surgical Lasers (K932981, K923575, K914991, K914136, K910037, K902990, K895518). The

operating platform in the Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers is also substantially equivalent to the operating platform in the Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers (K974789). The Coherent Delivery Devices are substantially equivalent to the previously cleared Coherent (K933318, K923575, K914991, K910037, K902990 and K895518) and TTI Medical (K952006) delivery devices. The Coherent Accessories (sterilization trays) are substantially equivalent to the sterilization tray in the Coherent SlimLine Single Lumen Aspiration Needle Kit (K960413).

VII. Safety and Effectiveness Information

Safety and effectiveness information was provided to demonstrate that the Modified Coherent VersaPulse Select Single Wavelength (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; endonasal surgery; gynecological surgical; and general surgery; for Ho:YAG and urology; general surgery; gastroenterology; thoracic and pulmonary surgery; ENT surgery; podiatry; orthopaedics; and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy for Nd:YAG.

VIII. Conclusion

The Modified Coherent VersaPulse Select Single Wavelength (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 Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories share the same indications for use, similar design features, and similar functional features as the currently marketed Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1999

Ms. Michelle P. Deeton
Senior Regulatory Affairs Associate
Coherent Medical Group
2400 Condensa Street
Santa Clara, California 95051-0901

Re: K990947
Trade Name: Modified Coherent VersaPulse Select Single Wavelength Ho:YAG
and Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers and Delivery
Devices with Accessories
Regulatory Class: II
Product Code: GEX
Dated: March 19, 1999
Received: March 22, 1999

Dear Ms. Deeton:

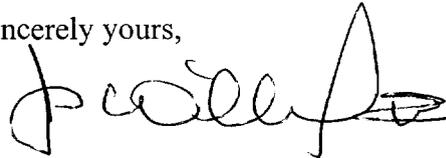
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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

Enclosure

Attachment 4
Indications For Use Statement as Requested by FDA

510(k) Number (if known): K990947
Device Name : Modified Coherent VersaPulse Select Single Wavelength Ho:YAG and
 Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers and Delivery
 Devices with Accessories

Indications For Use:

The modified and currently marketed Coherent VersaPulse Select Single Wavelength (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; endonasal surgery; gynecological surgery; and general surgery; and
- Nd:YAG - urology; general surgery; gastroenterology; thoracic and pulmonary surgery; ENT surgery; podiatry; orthopaedics; and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy.

The modified and currently marketed Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (and the delivery accessories that are used with them to deliver laser energy) are indicated for use in the performance of specific surgical applications in urology, urinary lithotripsy, arthroscopy/orthopaedics, discectomy, endonasal surgery/ENT surgery, gynecological surgery/gynecology, general surgery, gastroenterology, thoracic and pulmonary surgery, dermatology and plastic surgery, podiatry, and limited indications in gynecology, neurosurgery, ophthalmology, and lumbar discectomy as follows:

Ho:YAG - Urology

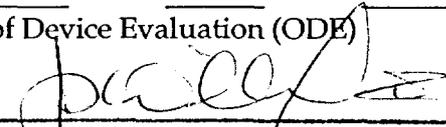
- Endoscopic holmium laser resection of the prostate (HoLRP) with the VersaPulse Select Ho:YAG and Ho:YAG/Nd:YAG Surgical Lasers for treatment of benign prostatic hypertrophy (BPH)

***** Indications For Use Continued on Next Page (6 pages total) *****

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990947

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

Attachment 4 - Continued
Indications For Use Statement as Requested by FDA

510(k) Number (if known): _____

Device Name : Modified Coherent VersaPulse Select Single Wavelength Ho:YAG and
Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers and Delivery
Devices with Accessories

Indications For Use Continued:

Ho:YAG - Urology - Continued

- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
 - bladder;
 - urethral and ureteral tumors;
 - condylomas;
 - lesions of external genitalia;
 - urethral and penile hemangioma;
 - urethral strictures;
 - bladder neck obstructions.

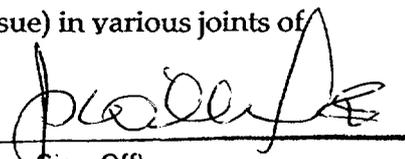
- Urinary Lithotripsy including:
 - endoscopic fragmentation of urinary calculi in the ureter or ureteropelvic junction;
 - treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

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 - Arthroscopic Surgery/Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft tissue) in various 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.



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Division of General Restorative Devices
510(k) Number 16990947

Prescription Use _____
(Per 21 CFR 801.109)

*** Indications For Use Continued on Next Page (page 2 of 6) ***

Attachment 4 - Continued
Indications For Use Statement as Requested by FDA

510(k) Number (if known): _____
Device Name : Modified Coherent VersaPulse Select Single Wavelength Ho:YAG and
Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers and Delivery
Devices with Accessories

Indications For Use Continued:

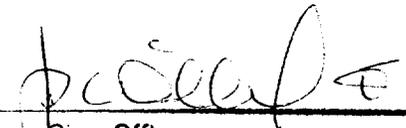
- Discectomy including:
 - percutaneous vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine;
 - open and arthroscopic spine procedures.

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;



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 159090

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.

Prescription Use X
(Per 21 CFR 801.109)

- 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;

***** Indications For Use Continued on Next Page (page 3 of 6) *****

Attachment 4 - Continued
Indications For Use Statement as Requested by FDA

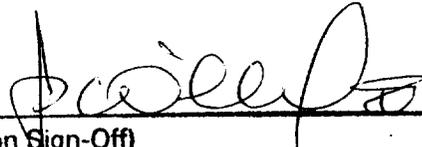
510(k) Number (if known): _____
Device Name : Modified Coherent VersaPulse Select Single Wavelength Ho:YAG and
Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers and Delivery
Devices with Accessories

Indications For Use Continued:

- appendectomy;
- removal of benign and malignant lesions;
- biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon.

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;
 - 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.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number E99094

Prescription Use _____
(Per 21 CFR 801.109) **X**

Ho:YAG - Endonasal Surgery

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

*** Indications For Use Continued on Next Page (page 4 of 6) ***

Attachment 4 - Continued
Indications For Use Statement as Requested by FDA

510(k) Number (if known): _____

Device Name : Modified Coherent VersaPulse Select Single Wavelength Ho:YAG and
Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers and Delivery
Devices with Accessories

Indications For Use Continued:

Nd:YAG - Ear, Nose and Throat (ENT) 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).

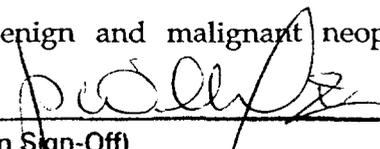
Nd:YAG - Gynecological Surgery

- 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.

Nd:YAG - Gastroenterologic Surgery

- Gastroenterologic 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.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General Restorative Devices
510(k) Number _____

199094

*** Indications For Use Continued on Next Page (page 5 of 6) ***

