SEP 1 1998

K981952

Instruments for Medicine and Diagnostics
3959 South 1820 West
Salt Lake City, Utah 84104
(801) 972-0500
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William J McMahan,Ph.D., President
Preparation Date: June 01, 1998

Summary of Safety and Effectiveness for the:

Trade Name: Combination Neodymium (Nd:)YAG and Solid State Green, Frequency Doubled Nd:YAG Surgical Laser System.

Common Name: Spectrum Veinlase

Classification Name: Laser Instrument, Surgical Powered - 79GEX

Legally Marketed Predicate Devices for Substantial Equivalence:

Coherent, "VersaPulse" Nd:YAG Solid State Q - Switched.

Thermolase "Softlight" Nd:YAG Laser Hair Removal & Skin Resurfacing Laser.

Laserscope Orion Series Surgical Laser System.

Cynosure "PhotoGenica LPIR" Dermatologic Laser

Rationale for SE: The Spectrum Veinlase and Delivery Devices share similar indications for use, and similar design features including; wavelengths, beam integrity, cooling system, control systems such as interlock devices, and displays. Functional features such as; delivery power, pulse rates, energy type, spot sizes, and areas for treatment are also similar. The legally marketed devices include the above listed systems and their 510(k) number.

Description of Submitted Device:

The Combination Nd:YAG and Solid State, (Frequency Doubled Nd:YAG) Surgical Laser System is an instrument used in the application of photocoagulation of soft tissue using a 532*nm* wavelength. The system has the ability to use a 1064*nm* wavelength for applications including; Coagulation, Vaporization, and Cutting. The system can run both wavelengths in "Captured Pulse" which delivers high energy at very short pulse durations. The laser light is "pumped" by flashlamp technology.

Technological Characteristics and Substantial Equivalence:

The Coherent, VersaPulse uses Q-switched frequency doubled, Q-switched Nd:YAG, and Q-switched Alexandrite:YAG laser energy to deliver 532*nm*, 1064*nm* and 755*nm* wavelengths. The VersaPulse delivers the same wavelength, similar average power, pulses of equivalent duration, and treatment spots of equivalent diameter. The indications for use are also similar.

TheThermolase Softlight Laser uses the identical wavelength. A Nd:YAG Rod, the output of which is 1064*nm*. The Softlight laser uses a carbon-based cream to aid in the removal of unwanted body hair and for skin resurfacing.Similar average power, pulses of equivalent duration, and treatment spots of equivalent diameter.

The Laserscope Orion Series Laser System offers the same 532/1064 capability and is capable of the pulsed power technology that we are offering.It is indicated in the treatment of dark ink tatoos. The laser delivers similar strength, similar average power, pulses of equivalent duration, and treatment spots of equivalent diameter.The "Starpulse" allows it to deliver high energy at short pulse durations.

The Cynosure PhotoGenica LPIR Laser uses a 755*nm* wavelength, obtained from a Flashlamp-Excited Solid State Pulsed Laser. This laser is indicated in the treatment of leg veins that are between 0.6 mm to 3.0 mm in size. The LPIR uses a HeNe (CW) 543*nm* green aiming beam. Other areas of the PhotoGenica LPIR including; pulse duration, and treatment spots are equally similar.

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Nonclinical Performance Data:

None

Clinical Performance Data:

None

Conclusion:

The Combination Nd:YAG and Solid State Green (Frequency Doubled Nd:YAG) Surgical Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for the treatment of Indicated uses listed.

Additional Information:

None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1998

William J. McMahan, Ph.D.
President
Instruments for Medicine and Diagnostics
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K981952

Trade Name: Combination Neodymium (Nd:) Yag and Solid State Green, Frequency Doubled Nd: YAG Surgical Laser System
Regulatory Class: II
Product Code: GEX
Dated: June i, 1998
Received: June 3, 1998

Dear Dr. McMahan:

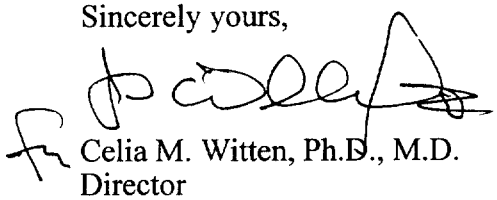
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

510(k) Number (if known): K980952

Device Name: Combination Nd:YAG and Solid State Green (Frequency Doubled Nd:YAG) Surgical Laser System

Indications For Use:

532nm Wavelength:

General Surgery:	**Coagulation, hemostasis, vaporization, excision, and incision of tissue. Photocoagulation of Vessels/Veins up to 1.5 mm**
Endoscopic & Laparoscopic:	**Excising, Coagulation or Vaporization of tissue during Endoscopic or Laparoscopic procedures, Cholecystectomy and Appendectomy.**
Gynecology:	**Ablation or lysis of intra-abdominal tissues via laparotomy or laparoscope. Ablation of endometrial implants, lysis of adhesions, ablation of the uterosacral ligaments, cutting/coagulating, treatment of uterine polyps and fibroids, salpingo-ophorolysis, and transection of uterine septa.**
Laryngology:	**Photocoagulation or Vaporization of soft or fibrous tissue such as; hereditary hemorrhagic telangiectasia (vascular lesions), pigmented structures that are highly vascular, and tonsillectomy.**
Otology:	**For; stapedotomy, stapedectomy, tympanoplasty with fascia graft, myringotomies, control of bleeding, removal of osseous disease of the external canal, removal of acoustic neuromas, lysis of adhesions and soft tissue adhesion, in both micro- and macro- otologic procedures.**
Rhinology:	**For; control of epistaxis, turbinate reduction (excludes bone), treatment of endonasal polyps, hereditary hemorrhagic telangiectasia, synechia, hemangiomas, telangiectasia, vaporize of maxillary sinus cysts and polyps, treatment of papillomas and granulomas, endonasal dacryocystorhinostomy, treatment of lesions within the nose and sinus, creation of nasoantral window and coagulation of vessels or veins up to 1.5 mm in diameter.**
Urology:	**Coagulation of veins or vessels up to 1.5 mm in diameter, management of condyloma acuminata, carcinoma in situ, small papillary bladder tumors, port wine stains, hemangioma of the external genitalia or bladder and urethral recanalization.**

Prescription Use X OR [redacted] ounter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980952

Neurosurgery:	**For; dorsal root entry zone lesions, spinal intramedullary tumor, medulloblastomas, acoustic neuromas, intracranial meningiomas, ventricular ependymomas, choroid plexus, carcinomas, hemangioblastomas, ependymoma extending into the brain stem, and intra- / extra- axial spinal cord tumors.**
Ophthalmology:	**For; posterior and anterior treatment procedures including; diabetic retinopathy, retinal detachments, ablate tissues of the iris or trabeculum, peripheral iridectomy and iridotomy, trabeculoplasty, and senile macular degeneration. Other conditions of the retina in which the laser is deemed useful involving endophotocoagulation. Extraorbital procedures such as; coagulation of vessels or veins up to 1.5 mm in diameter, extra orbital pigmented or venous lesions; port wine hemangiomas or telangiectasia. Treatment for chronic dacryocystitis.**
Dermatology:	**For; treating vascular lesions, dermatologic lesions, and/or cutaneous lesions such as; facial or extremities telangiectasias, venous anomalies, leg veins up to 1.5 mm in diameter, and port wine stains.**

1064nm Wavelength:

General Surgery:	**For; incision or excision of all soft body tissues including; skin, subcutaneous and breast tissue, striated and smooth muscle, tendon and fascia, cartilage, mucous membrane, lymphatic tissue, internal organs and glands of the gastrointestinal, genitourinary, pulmonary, endocrine and exocrine systems, as well as cancers of theses systems. Treatment of larger and deeper vessels/veins up to 3.0 mm in diameter, 4.0 to 7.0 mm in depth.**
ENT, Head & Neck:	**For; incision or excision of all soft body tissues including; skin, subcutaneous tissue, striated and smooth muscle, tendon and fascia, cartilage, mucous membrane, lymphatic tissue, organs and glands of the ENT system and access via endoscope, microscope or direct visualization.**
Gastroenterology:	**For; esophageal neoplastic obstructions such as; squamous cell carcinoma, and adenocarcinoma, upper and lower GI bleeding such as; varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, stomach ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions and hereditary hemorrhagic telangiectasia. Papilliation of unresectable mucosal-based cancers, coagulation of arteriovenous malformations, ablation of; adenomatous polyps, benign and malignant neoplasm, angiodysplasia, polyps, ulcers, colitis and hemorrhoids. Recanalization of obstructing lesions throughout the gastrointestinal tract, and endoscopic treatment of early oesophageal or gastric cancer.**

Gynecology:	**For; endometrial ablation, treatment of menorrhagia, treatment of endometrotic implants, lysis of adhesions, treatment of cervical, vaginal, or vulvar dysplasia, and treatment of cervical, vaginal, or vulvar condyloma.**
Neurology:	**For; treatment of arterio-venous malformations, and vascular intracranial tumors like meningiomas and metastatic spinal tumors.**
Pulmonary:	**For; treatment of benign and malignant tracheobronchial lesions in the pulmonary airway including; squamous cell carcinoma, papillomas, adenocarcinoma, granulomas, and tracheal stenosis.**
Urology:	**Treatment of superficial and invasive bladder carcinoma, urethral and ureteral strictures, benign or malignant lesions of the external genitalia, urethra and anus (condyloma acuminata), bladder neck contracture, and diverticulum.**
Dermatology:	**Photocoagulation of vascular lesions for the reduction of lesion size. Treatment of vascular lesions such as; port wine stains (PWS), hemangiomas, angiomas, and venous anomilies. Incision/Excision of soft body tissues.**
Otolaryngology:	**Bronchoscopy procedures such as; photocoagulation of endobronchial tumors.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number [redacted]

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Indications for use, Spectrum Veinlase