



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Blueshine SRL
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street Northwest
Buffalo, Minnesota 55313

APR 14 2009

Re: K090297

Trade/Device Name: Blueshine GOLD series Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 9, 2009
Received: April 9, 2009

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

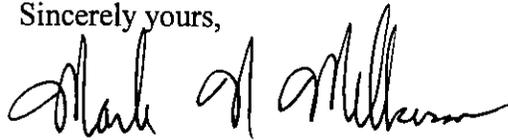
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) : K090297

Device Name: Blueshine GOLD series

Indications For Use:

980 nm Wavelengths

The Blueshine GOLD series , (and the fiber delivery systems and accessories used to deliver laser energy), is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery.

The Blueshine GOLD series Laser is indicated for use in the performance of specific surgical applications in gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery as follows:

Gastroenterology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include: hemostasis of esophageal varices; palliation of malignant dysphagia; palliative ablation of obstructive neoplasms; hemostasis of colonoscopy.

Neurosurgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include: tumors adjacent to the spinal cord; tumors adjacent to the cortex.

General Surgery

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein. The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include: Laparoscopic: appendectomy; cholecystectomy; bowel resection. Open: mastectomy; reduction mammoplasty; breast biopsy; rectal and anal hemorrhoidectomy; bowel resection; colectomy; cholecystectomy; liver resection; condyloma; thyroidectomy; thoracotomy; cavernous hemangioma.

Genitourinary (Urology)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include: Transurethral: transurethral incision of the prostate (TUIP); bladder tumors; bladder neck

Mike P. [unclear] for [unclear]
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K090297

incisions; urethral strictures; exterior sphincterotomy. Laparoscopic lymphadenectomy. Open: condyloma; circumcision; benign and malignant lesions of external genitalia

Thoracic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection; coagulation of blebs and bullae; adhesiolysis; pericardiectomy; mediastinal and thoracic lesions and abnormalities; mediastinal lymph node dissection; hemostasis; thoracotomy.

Gynecology (GYN)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic excision/lysis of adhesions; endometrial lesions, including ablation of endometriosis; laparoscopic assisted hysterectomy (LAVH); laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy; ovarian drilling; tubal fimbrioplasty; appendectomy. Open: conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN; condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

Pulmonology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

Ophthalmology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics; open DCR; endo-nasal DCR; tumor excision and biopsy; eyelid reconstruction; blepharoplasty.

Orthopedics

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: Open: Dissect and coagulate.

Otolaryngology (ENT)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus: turbinectomy and turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy; Laryngo-tracheal: removal of vocal cord/fold nodules, polyps and cysts; arytenoidectomy; tracheal stenosis; Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemi glossectomy; Head & Neck: tumor resection on oral, subfacial and neck tissues; parathyroidectomy; thyroidectomy.

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

510(k) Number K090297

In addition the Blueshine GOLD series Laser is intended for **Laser Assisted Lipolysis**

Prescription Use: X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use:
(Part 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden, Sr.
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K090297