DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

ProSurg, Inc.
c/o Mr. Ashvin Desai
Manager, Regulatory Affairs
2195 Trade Zone Boulevard
San Jose, CA 95131

Re: K060326
Trade/Device Name: LaserTx™ - Diode Laser & Delivery 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 (two)
Product Code: OCL, GEX
Dated: February 2, 2006
Received: February 15, 2006

Dear Mr. Desai:

This letter corrects our substantially equivalent letter of April 5, 2006.

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 (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 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 continue 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Indications for Use

510(k) Number (if known): K060326

Device Name: LaserTx™ - Laser & Delivery System

Indications for Use:

The LaserTx Diode Laser System is intended for delivery of laser light to soft tissue in contact or non contact mode during surgical procedures, including via endoscopes, introducers, or catheters.
The LaserTx laser system is generally indicated for incision, excision Vaporization, ablation, hemostatis or coagulation of soft tissue In Ear, Nose and Throat and Oral surgery (Otolaryngology), Dental Procedures, Arthroscopy Gastroenterology, General Surgery, Dermatology Plastic surgery, Podiatry, Urology, Gynecology, Neurosurgery (Peripheral nervous system) Pulmonary surgery and cardiothoracic surgery.
The LaserTx Diode laser system can be used with fiber optic laser delivery devices and photosensitizing agents & chromophores to enhance target tissue effects and photo selective application during surgical procedures.
The LaserTx Diode Laser system is indicated for incision, excision, vaporization, hemostatis coagulation, ablation of soft tissue, tumors, strictures, obstructions in body organs including urethra, bladder, prostate, uterus, breast, stomach, colon, abdomen, veins lung, brain, ear, nose throat etc.
For additional indications for use please refer to attachment.
(Additional Indications, identical to predicated device cleared by FDA under 510K application # K032864)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of General, Restorative, and Neurological Devices

510(k) Number K060326

510(k) NUMBER (IF KNOWN): K060326

DEVICE NAME: LaserTx™ - Diode Laser & Delivery System

INDICATIONS FOR USE:

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)

Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

Arthroscopy

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

- Menisectomy
- Synovectomy
- Chondromalacia

Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

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

510(k) Number K060326

General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and homeostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorapphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Phototcoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

Urology

Excision, vaporization, incision, coagulation, ablation and homeostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include: homeostasis in conjunction with menigiomas

Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue.

Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

Dental Applications

Indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use with the ELVes Procedure Kit in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

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

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

510(k) Number K060326