

K091909

510(k) SUMMARY

Title: Quanta System LITHO Laser System

JUL - 9 2009

Submitter: Quanta System SpA
via IV Novembre,116
21058 Solbiate
Olona VA / Italy

Contact: Dr. Isabella Carrer
Medical Division Manager

Date Prepared: April 10, 2009

Device Trade Name: Quanta System LITHO Laser System

Common Name: Laser surgical instrument for use in general surgery and dermatology

Classification Name: Instrument, surgical, powered, laser

Predicate Devices: - AllMed System Sphinx Laser System
(K033437);

Intended Use /
Indications for Use: 2.1 μ m Applications:

The LITHO laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotnpsy, Gastroenterology, Arthroscopy, Discetomy Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral

- Tumors,
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Holmium Laser Resection of the Prostate (HoLRP)
- Holmium Laser Enucleation of the Prostate (HoLEP)
- Holmium laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy

- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
- dehydrate stones.
- Endoscopic fragmentation of kidney calculi
- Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease

- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including:

- Ligament and tendon Release
- Countouring and sculpting of articular surfaces
- Capsulectomy in the Knee
- Chondreplasty in the Knee
- Debridement of inflamed synovial tissue
- Chondromalacia Ablation
- Chondromalacia and tears
- Plica Removal
- Meniscectomy
- Loose Body Debridement
- Lateral retinecular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including

- Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-S1 lumbar discs, including Foraminoplasty
- Percutaneous Cervical Disc Decompression/Discectomy
- Percutaneous Thoracic Disc Decompression/Discectomy

Pulmonary

Open and endoscopic pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue)

Gynecology

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

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and cartilage) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

Dermatology and Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas
- Lesions of skin and subcutaneous tissue
- Skin tags
- Plantar warts
- Lesions of skin and subcutaneous tissue
- Port Wine Stains
- Papillomas

General Surgery

Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Skin incision
- Excision of external and internal lesions
- Complete or partial resection of internal organs, tumors and lesions
- Biopsy

Technological Characteristics:

The LITHO Laser System is a surgical laser instrument for use in general surgery and dermatology.

The LITHO Laser System includes 1 model:

Models	Wavelength	Laser Power
LITHO	2.1 μ m	30W

The LITHO laser system is designed with five major sub-systems, including: (1) **Power Supply**: a high voltage power supply, which converts and rectifies the AC mains current to provide regulated power for the flash lamp simmer current and main triggering pulse; (2) **Cooling System**: a cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger; (3) **Laser System**: an Ho:YAG laser rod, capable of generating laser pulses at 2.1 μ m wavelength and a frequency up to 20 Hz; (4) **Delivery System**: an optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and focusing hand piece; (5) **Display and Control Electronics**: a display with control electronics, which regulates the functions of the laser and allows parameter selection by the user.

In addition to the five subsystems, the LITHO laser system incorporates several safety features, including a remote interlock, an emergency red push button, a footswitch and a key switch.

Performance Data

None

**Substantial
Equivalence:**

The Quanta System LITHO Laser System is as safe and effective as the predicate device. The LITHO Laser System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the LITHO Laser System and its predicate devices raise no new issues of safety or effectiveness. Thus, the LITHO Laser System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Quanta System, S.P.A.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

JUL - 9 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K091909

Trade/Device Name: LITHO 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: June 24, 2009

Received: June 25, 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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

Page 2 - Mr. Mark Job

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 091909

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Neil R. Dyer for rxm
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

Gastroenterology

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Decompression/Discectomy Percutaneous Thoracic Disc
Decompression/Discectomy

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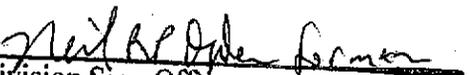
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Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(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. Ogle, Sr. M.D.
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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