

SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

APR 21 2010

K100415

(Premarket Notification [510(k)] Number)

Date of Preparation: 12 April 2010

1. Applicant

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Corresponding Official:

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2. Device Name

Device Name: AcuPulse 30/40ST CO2 Laser Systems and
AcuPulse 40WG CO2 Laser System

Device trade or proprietary name: CO2 Laser System

Common Name: CO2 Laser System

Classification Name: Laser Surgical Instrument, 21 CFR Section
878.4810

3. Predicate Devices

The modified CO2 Laser WaveGuide is substantially equivalent to the following device:

510(k) No.	Manufacturer	Device
K082809	Lumenis Ltd.	AcuPulse 30/40 ST CO2 Laser Systems

4. Indications for Use

The intended use of the AcuPulse 30/40 ST CO2 Laser Systems and AcuPulse 40WG CO2 Laser series is for the vaporization, incision, excision, ablation or photocoagulation of soft tissue in the surgical specialties of: ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry.

The intended use of the AcuPulse series is for the performance of specific surgical applications in the surgical specialties of ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry as follows:

Dermatology

The AcuPulse laser is indicated for use in dermatology and plastic surgery for the following applications:

- Ablation, vaporization, excision, incision and coagulation of soft tissue in the performance of:
 - Laser skin resurfacing
 - Laser dermabrasion
 - Laser burn debridement
- Laser skin resurfacing (ablation and/or vaporization) for the treatment of:
 - Wrinkles, rhytids and furrows (including fine lines and texture irregularities).
- Laser skin resurfacing (ablation, and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
 - Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci wart and verruUT seborrheica.
 - Vermillionectomy of the lip
 - Cutaneous horns
 - Solar/actinic elastosis
 - Cheilitis, including actinic cheilitis
 - Lentiginos, including lentigo maligna or Hutchinson's malignant freckle
 - Uneven pigmentation/dyschromia
 - Acne scars
 - Surgical scars
 - Keloids including acne keloidalis nuchae
 - Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum)
 - Tattoos
 - Telangiectasia
 - Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
 - Superficial pigmented lesions
 - Adenosebaceous hypertrophy or sebaceous hyperplasia
 - Rhinophyma reduction
 - Cutaneous papilloma (skin tags)

- Milia
- Debridement of eczematous or infected skin
- Basaloid and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
- Nevi, including spider, epidermal and protruding
- Neurofibromas
- Laser de-epithelialization
- Trichoepitheliomas
- Xanthelasma palpebrarum
- Syringoma
- Laser ablation, vaporization, and/or excision for complete and partial nail matrixectomy
- Vaporization/coagulation of:
 - Benign/malignant vascular/avascular skin lesions
 - Moh's surgery
 - Lipectomy
 - Verrucae and seborrhoecae vulgares, including paronychial, periungual and subungual warts
- Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty
- Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

The AcuPulse laser is indicated for use in podiatry for the following applications:

- Laser ablation, vaporization, and/or excision of soft tissue for the reduction, removal, and/or treatment of:
 - Verrucae vulgares/plantar (warts), including paronychial, periungual and subungual warts
 - Fungal nail treatment
 - Porokeratoma ablation
 - Ingrown nail treatment
 - Neuromas/fibromas, including Morton's neuroma
 - Debridement of ulcers
 - Other soft tissue lesions
- Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy

Otolaryngology (ENT)

The AcuPulse laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for the treatment of:

- Choanal atresia
- Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue

- Nasal obstruction
- Adult and juvenile papillomatosis polyps
- Polypectomy of nose and nasal passages
- Lymphangioma removal
- Removal of vocal cord/fold nodules, polyps and cysts
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords.
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue
- Zenker's Diverticulum/pharyngoesophageal diverticulum (endoscopic laser-assisted esophagodiverticulostomy (ELAED))
- Stenosis, including subglottic stenosis
- Tonsillectomy (including tonsillar cryptolysis and neoplasia) and tonsil ablation/tonsillotomy
- Pulmonary bronchial and tracheal lesion removal
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial)
- Benign and malignant lesions and fibromas (nose and nasal passages)
- Benign and malignant tumors and fibromas (oral)
- Stapedotomy/Stapedectomy
- Acoustic neuroma in the ear
- Superficial lesions of the ear, including chondrodermatitis nodularis chronica/helices/Winkler's disease
- Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue)
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea
- Myringotomy/tympanostomy (tympanic membrane fenestration)
- Uvulopalatoplasty (LAUP, laser UPPP)
- Turbinectomy and turbinate reduction/ablation
- Septal spur ablation/reduction and septoplasty
- Partial glossectomy
- Tumor resection of oral, subfacial and neck tissues
- Rhinophyma
- Verrucae vulgares (warts)
- Gingivoplasty/gingivectomy

Gynecology and GYN Laparoscopy Indications

The AcuPulse laser is indicated for use in gynecology for the following applications:

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
 - Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN)

- Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowenoid papulosa (BP lesions)
- Leukoplakia (vulvar dystrophies)
- Incision and drainage (I&D) of Bartholin's and nabothian cysts
- Herpes vaporization
- Urethral caruncle vaporization
- Cervical dysplasia
- Benign and malignant tumors
- Hemangiomas
- Vaporization, incision, excision, ablation or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:
 - Endometrial lesions, including ablation of endometriosis
 - Excision/lysis adhesions
 - Salpingostomy
 - Oophorectomy
 - Fimbrioplasty
 - Metroplasty
 - Microsurgery (tubal)
 - Uterine myomas and fibroids
 - Ovarian fibromas and follicle cysts
 - Uterosacral ligament ablation
 - Hysterectomy

Neurosurgery Indications

The AcuPulse laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of:

- Cranial
 - Posterior fossa tumors
 - Peripheral neurectomy
 - Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors
 - Arteriovenous malformation
 - Pituitary gland tumors (transphenoidal approach)

- Spinal cord
 - Incision/excision and vaporization of benign and malignant tumors and cysts
 - Intra and extradural lesions
 - Laminectomy/laminotomy/microdiscectomy

Orthopedic Indication

The AcuPulse Laser is indication for incision, excision and vaporization of soft tissue in orthopedic surgery, including the following applications:

- Arthroscopy
 - Meniscectomy
 - Chondromalacia
 - Chondroplasty
 - Ligament release (lateral and other)
 - Excision of plica
 - Partial synovectomy

- General
 - Debridement of traumatic wounds
 - Debridement of decubitus and diabetic ulcers
 - Microsurgery
 - Artificial joint revision
 - PMMA removal

General and Thoracic Surgery

The AcuPulse Laser is indication for the incision, excision and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures. Applications include:

- Debridement of decubitus ulcers stasis, diabetic, and other ulcers
- Mastectomy
- Debridement of burns
- Rectal and anal hemorrhoidectomy
- Breast biopsy
- Reduction mammoplasty
- Cytorreduction for metastatic disease
- Laparotomy and laparoscopic applications
- Mediastinal and thoracic lesions and abnormalities
- Skin tag vaporization
- Atheroma
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

Dental and Oral Surgery

The AcuPulse Laser is indication for the incision, excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- Gingivectomy/removal of hyperplasias
- Gingivoplasty

- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- Operculectomy
- Crown lengthening
- Removal of soft tissue, cysts and tumors
- Oral cavity tumors and hemangiomas
- Abscesses
- Extraction site hemostasis
- Salivary gland pathologies
- Preprosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

5. Description of the Device

The AcuPulse 30/40 (ST and WG) CO2 Laser systems provide up to 30 or 40 Watts (model dependent) on tissue. The systems incorporate the following components:

- The CO2 laser tube within the main cabinet,
- An articulated arm beam delivery system (AcuPulse 30/40 ST) or a new short arm that may be used with a WaveGuide beam delivery system (AcuPulse 40WG).
- A footswitch for laser activation;
- A laser beam wavelength of 10.6 μm .

The AcuPulse CO2 40WG Laser system contains a short arm, WaveGuide port which connects to the Fiberlase CO2 Laser WaveGuide beam delivery system. The WaveGuide port is a rigid, fixed position arm with an internal adjustable folding mirror. The tip of the WaveGuide port has a 905 SMA connector to connect to the WaveGuide. The WaveGuide port contains a small WaveGuide support arm to support the WaveGuide during use. Additionally, the AcuPulse CO2 40WG Laser system may be used with an articulating WaveGuide Support Arm to support the WaveGuide when not in use. The WaveGuide Support Arm is clamped at one end to the rear handle of the laser system and contains a receptacle at the other end, into which the WaveGuide hand piece may be placed when not in use.

The AcuPulse CO2 Laser system series are offered with the following three basic modes of laser energy:

- Continuous Wave (CW) Mode

The continuous wave mode is optimal for incision or ablation where homeostasis is desirable as it delivers a continuous, steady beam of energy.

- Pulser Mode

The pulser mode high-frequency delivers pulses in a contract present pulse frequency for enhanced tissue incision capability as controlled by varying the ON time. Thermal damage to surrounding tissue is usually reduced with shorter laser activation durations, whereby the adjacent healthy tissue has more time to cool between pulses.

- SuperPulse Mode

The superpulse mode is optimal for incision or ablation where char-free performance is desirable. This includes many dermal applications. SuperPulse is a continuous series of short duration, peak power pulses whose average power is the set power. The SuperPulse laser rapidly vaporizes the target tissue so only a negligible amount of heat is transferred (by conduction) to adjacent tissue.

6. Technological Characteristics Compared to Predicate Device

The new AcuPulse 30/40 (ST and WG) CO2 Laser systems and the previously cleared AcuPulse (30 and 40 ST) series have the same basic components of a seal-off, DC excited CO2 laser system. The only differences are a slight change to the optical bench assembly and the software version. Also, the new AcuPulse 40WG CO2 Laser system is supplied with a new short arm, WaveGuide Port instead of the articulating arm beam delivery system provided in the AcuPulse 30/40 ST laser system series and is intended to be used with the Fiberlase CO2 Laser WaveGuide.

In summary, the technological characteristics of the modified device, e.g., overall design, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the new AcuPulse 30/40 (ST and WG) CO2 Laser systems are substantially equivalent to the previously cleared AcuPulse 30/40 (ST) CO2 Laser system cited above. The minor differences were tested as part of the performance data included in the 510(k).

7. Performance Testing

The following verification and/or validation activities were performed and submitted as part of the 510(k):

- IEC 60601-1 – Medical Electrical Equipment, Part 1: General Requirements for Safety 1988, Amendments #1 (1991) and #2 (1995);
- IEC 60825-1 - Safety of laser products, Part 1: Equipment classification and requirements;

- IEC 60601-2-22 – Medical Electrical Equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;
- IEC 60601-1-2 - Medical Electrical Equipment, Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests (+A1:2004); and
- Software Validation of new Software version.

The results of the performance tests demonstrated that the AcuPulse 30/40 (ST and WG) CO2 Laser systems comply with the above testing standards IEC 60601-1, IEC 60825-1, IEC 60601-2-22 and IEC 60601-1-2. The software validation demonstrated that the new software version met the software requirements specifications.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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APR 21 2010

Re: K100415

Trade/Device Name: AcuPulse 30/40ST CO2 Laser Systems and
AcuPulse 40WG CO2 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
Plastic surgery and dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 02, 2010
Received: February 16, 2010

Dear Ms. Stein:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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.

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" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm> 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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1 – INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 100415

Device Name: AcuPulse 30/40 ST and 40WG CO2 Laser System

Indications for use:

The intended use of the AcuPulse 30/40 ST CO2 Laser Systems and AcuPulse 40WG CO2 Laser series is for the vaporization, incision, excision, ablation or photocoagulation of soft tissue in the surgical specialties of: ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry.

The intended use of the AcuPulse series is for the performance of specific surgical applications in the surgical specialties of ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry as follows:

Dermatology

The AcuPulse laser is indicated for use in dermatology and plastic surgery for the following applications:

- Ablation, vaporization, excision, incision and coagulation of soft tissue in the performance of:
 - Laser skin resurfacing
 - Laser dermabrasion
 - Laser burn debridement
- Laser skin resurfacing (ablation and/or vaporization) for the treatment of:
 - Wrinkles, rhytids and furrows (including fine lines and texture irregularities).
- Laser skin resurfacing (ablation, and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
 - Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci wart and verruUT seborrheica.
 - Vermillionectomy of the lip
 - Cutaneous horns
 - Solar/actinic elastosis
 - Cheilitis, including actinic cheilitis
 - Lentigines, including lentigo maligna or Hutchinson’s malignant freckle
 - Uneven pigmentation/dyschromia
 - Acne scars
 - Surgical scars
 - Keloids including acne keloidalis nuchae
 - Hemangiomas (including Buccal, port wine and pyogenic granulomas, pyogenicum/granuloma telangiectaticum)


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Dermatology (con't)

- Tattoos
- Telangiectasia
- Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
- Superficial pigmented lesions
- Adenosebaceous hypertrophy or sebaceous hyperplasia
- Rhinophyma reduction
- Cutaneous papilloma (skin tags)
- Milia
- Debridement of eczematous or infected skin
- Basaloid and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
- Nevi, including spider, epidermal and protruding
- Neurofibromas
- Laser de-epithelialization
- Trichoepitheliomas
- Xanthelasma palpebrarum
- Syringoma
- Laser ablation, vaporization, and/or excision for complete and partial nail matrixectomy
- Vaporization/coagulation of:
 - Benign/malignant vascular/avascular skin lesions
 - Moh's surgery
 - Lipectomy
 - Verrucae and seborrhoecae vulgares, including paronychial, periungual and subungual warts
- Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty
- Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

The AcuPulse laser is indicated for use in podiatry for the following applications:

- Laser ablation, vaporization, and/or excision of soft tissue for the reduction, removal, and/or treatment of:
 - Verrucae vulgares/plantar (warts), including paronychial, periungual and subungual warts
 - Fungal nail treatment
 - Paronychia ablation
 - Ingrown nail treatment
 - Neuromas/fibromas, including Morton's neuroma
 - Debridement of ulcers
 - Other soft tissue lesions
- Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy


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Otolaryngology (ENT)

The AcuPulse laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for the treatment of:

- Choanal atresia
- Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue
- Nasal obstruction
- Adult and juvenile papillomatosis polyps
- Polypectomy of nose and nasal passages
- Lymphangioma removal
- Removal of vocal cord/fold nodules, polyps and cysts
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords.
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue
- Zenker's Diverticulum/pharyngoesophageal diverticulum (endoscopic laser-assisted esophagodi-verticulostomy (ELAED))
- Stenosis, including subglottic stenosis
- Tonsillectomy (including tonsillar cryptolysis and neoplasma) and tonsil ablation/tonsillotomy
- Pulmonary bronchial and tracheal lesion removal
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial)
- Benign and malignant lesions and fibromas (nose and nasal passages)
- Benign and malignant tumors and fibromas (oral)
- Stapedotomy/Stapedectomy
- Acoustic neuroma in the ear
- Superficial lesions of the ear, including chondrodermatitis nodularis chroniUT helices/Winkler's disease
- Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue)
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea
- Myringotomy/tympanostomy (tympanic membrane fenestration)
- Uvulopalatoplasty (LAUP, laser UPPP)
- Turbinectomy and turbinate reduction/ablation
- Septal spur ablation/reduction and septoplasty
- Partial glossectomy
- Tumor resection of oral, subfacial and neck tissues
- Rhinophyma
- Verrucae vulgares (warts)
- Gingivoplasty/gingivectomy

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510(k) Number K100415

Gynecology and GYN Laparoscopy Indications

The AcuPulse laser is indicated for use in gynecology for the following applications:

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
 - Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN)
 - Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowenoid papulosa (BP lesions)
 - Leukoplakia (vulvar dystrophies)
 - Incision and drainage (I&D) of Bartholin's and nabothian cysts
 - Herpes vaporization
 - Urethral caruncle vaporization
 - Cervical dysplasia
 - Benign and malignant tumors
 - Hemangiomas
- Vaporization, incision, excision, ablation or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:
 - Endometrial lesions, including ablation of endometriosis
 - Excision/lysis adhesions
 - Salpingostomy
 - Oophorectomy
 - Fimbrioplasty
 - Metroplasty
 - Microsurgery (tubal)
 - Uterine myomas and fibroids
 - Ovarian fibromas and follicle cysts
 - Uterosacral ligament ablation
 - Hysterectomy

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 Division of Surgical, Orthopedic,
 and Restorative Devices

510(k) Number K100415

Neurosurgery Indications

The AcuPulse laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of:

- Cranial
 - Posterior fossa tumors
 - Peripheral neurectomy
 - Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors
 - Arteriovenous malformation
 - Pituitary gland tumors (transphenoidal approach)
- Spinal cord
 - Incision/excision and vaporization of benign and malignant tumors and cysts
 - Intra and extradural lesions
 - Laminectomy/laminotomy/microdiscectomy

Orthopedic Indication

The AcuPulse Laser is indication for incision, excision and vaporization of soft tissue in orthopedic surgery, including the following applications:

- Arthroscopy
 - Meniscectomy
 - Chondromalacia
 - Chondroplasty
 - Ligament release (lateral and other)
 - Excision of plica
 - Partial synovectomy
- General
 - Debridement of traumatic wounds
 - Debridement of decubitus and diabetic ulcers
 - Microsurgery
 - Artificial joint revision
 - PMMA removal

General and Thoracic Surgery

The AcuPulse Laser is indication for the incision, excision and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures. Applications include:

- Debridement of decubitus ulcers stasis, diabetic, and other ulcers
- Mastectomy
- Debridement of burns
- Rectal and anal hemorrhoidectomy
- Breast biopsy
- Reduction mammoplasty
- Cytoreduction for metastatic disease
- Laparotomy and laparoscopic applications
- Mediastinal and thoracic lesions and abnormalities
- Skin tag vaporization
- Atheroma
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips
- Pilondial cyst removal and repair
- Abscesses
- Other soft tissue applications

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and Restorative Devices

510(k) Number K100415

Dental and Oral Surgery

The AcuPulse Laser is indication for the incision, excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- Gingivectomy/removal of hyperplasias
- Gingivoplasty
- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- Operculectomy
- Crown lengthening
- Removal of soft tissue, cysts and tumors
- Oral cavity tumors and hemangiomas
- Abscesses
- Extraction site hemostasis
- Salivary gland pathologies
- Preprosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

Prescription Use √
(Per 21 C.F.R. 801.109)

OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden
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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number: K100415