

K082809

DEC 18 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name: Lumenis, Inc.
Address: 5302 Betsy Ross Drive
Santa Clara, CA 95054
Contact: Mark H. Smith
Phone: (408) 764-3615
Fax: (408) 764-3934
Date of Preparation: June 13, 2008

B. DEVICE NAME:

Trade Name(s): AcuPulse 30 and 40 Carbon Dioxide Laser System
Common/Usual Name: Laser instrument, surgical, powered
Classification Names: 79 GEX, Laser Powered Surgical Instrument
CFR Reference: 21 CFR 878.4810, Laser surgical instrument for use in general and plastic surgery and in dermatology

C. PREDICATE DEVICES NAMES:

Trade Name(s): 1) Sharplan Models 20C, 30C and 40C CO2 Laser (K963229)
2) UltraPulse SurgiTouch CO2 Laser Systems (K030147)

D. DEVICE DESCRIPTION:

The AcuPulse 30 and 40 series is the next generation of Lumenis CO2 lasers. The new product will retain the same console, articulated arm, delivery devices and other basic features of the current Compact 20C, 30C & 40C series, while integrating improved versions of the GUI and SurgiTouch scanner currently used with the UltraPulse SurgiTouch.

The AcuPulse 30 and 40 Carbon Dioxide Laser is an advanced computer-controlled, user friendly CO2 laser system based on a sealed-off CO2 laser tube providing up to 30 or 40 Watts (model dependent) on tissue. The system incorporates the CO2 laser tube within the main cabinet, an articulated arm beam delivery system and attachable laser accessories. The system is activated for laser emission by a footswitch.

This system incorporates a DC-excited CO2 laser tube. The CO2 laser wavelength falls in the mid-infrared region of the electromagnetic spectrum. This wavelength is invisible to the human eye. CO2 laser energy is readily absorbed by water in tissue. Since soft tissue is comprised primarily of water, CO2 laser energy can be used effectively for the excision, incision, ablation, vaporization and coagulation of soft tissue

The principles of operation and fundamental scientific technology are the same for the subject devices and predicate devices.

E. INTENDED USE:

The intended use of the AcuPulse series is for the vaporization, incision, excision, ablation, or coagulation 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, seborrheic wart and verruca 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
 - ⇒

Dermatology, continued

- ⇒ 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
- ⇒ Basal 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
- ⇒ Tricoepitheliomas
- ⇒ 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 paronychia, 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 paronychia, 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 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)
- 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 of 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 Indications

The AcuPulse laser is indicated 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 indicated for 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
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

Dental and Oral Surgery

The AcuPulse laser is indicated for 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

Both the subject and predicate devices have nearly identical indications for use and intended use:

Both the subject and predicate devices have the same indications for use and intended use.

The intended use has not changed from the predicate devices (K963229, K030147).

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE STATEMENT:

The subject device, the AcuPulse 30 and 40 Carbon Dioxide Laser System, has the same intended use, general design and fundamental scientific technology as the predicate devices (K963229, K030147).

The AcuPulse 30 and 40 Carbon Dioxide Laser System uses technology substantially equivalent to the Sharplan Models 20C, 30C and 40C CO₂ Laser (K963229), and the

UltraPulse SurgiTouch CO2 Laser Systems (K030147). There are no new hazards introduced by the AcuPulse 30 and 40 Carbon Dioxide Laser System as compared with the predicate devices.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the AcuPulse 30 and 40 Carbon Dioxide Laser System has been conducted.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Lumenis, Inc.
% Frances E. Harrison, RAC
Global VP, Regulatory Affairs
and Quality Compliance
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K082809

Trade/Device Name: AcuPulse 30 and 40 Carbon Dioxide 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: September 22, 2008
Received: September 24, 2008

Dear Frances E. Harrison:

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" (21 CFR 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

IFU Statement

510(k) Number (if known): K082809

Device Name: AcuPulse 30 and 40 Carbon Dioxide Laser System

Indications for Use:

The intended use of the AcuPulse series is for the vaporization, incision, excision, ablation, or coagulation 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.

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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, seborrheic wart and verruca 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

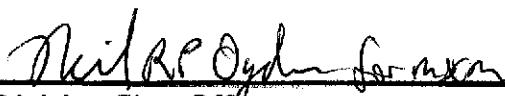
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Dermatology, continued

- ⇒ 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
- ⇒ Basal 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
- ⇒ Tricoepitheliomas
- ⇒ 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 seborrhoeae vulgares, including paronychia, 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

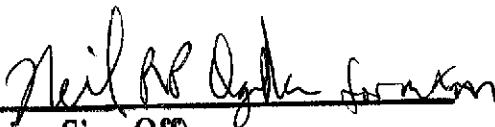

(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K082809

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 paronychia, 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



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**Division of General, Restorative,
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510(k) Number K082809

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 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)
- Acoustic neuroma in the ear
- Superficial lesions of the ear, including chondrodermatitis nondularis 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

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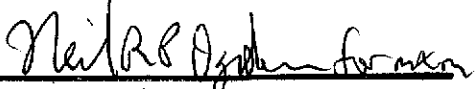
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and Neurological Devices**

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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 of adhesions
 - ⇒ Salpingostomy
 - ⇒ Oophorectomy
 - ⇒ Fimbrioplasty
 - ⇒ Metroplasty
 - ⇒ Microsurgery (tubal)
 - ⇒ Uterine myomas and fibroids
 - ⇒ Ovarian fibromas and follicle cysts
 - ⇒ Uterosacral ligament ablation
 - ⇒ Hysterectomy


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Neurosurgery Indications

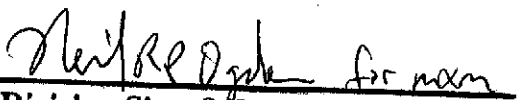
The AcuPulse laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of:

- 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 Indications

The AcuPulse laser is indicated 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


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General and Thoracic Surgery

The AcuPulse laser is indicated for 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
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

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and Neurological Devices**

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Dental and Oral Surgery

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

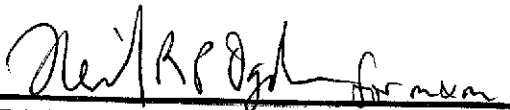
- Gingivectomy/removal of hyperplasias
- Gingivoplasty
- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- 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

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(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,
Over-The-Counter Use
and Neurological Devices**

Prescription Use X

AND/OR

(Recommended Format 11/13/2003)

510(k) Number K082809

