April 3, 2018

Lumenis Ltd.
Amaya De Levie
Head of Surgical Regulatory Affairs
6 Hakidma Street
P O Box 240
Yokneam, 2069204 Il

Re: K180597
Trade/Device Name: AcuPulse (previously called AcuPulse 30/40 ST); AcuPulse 40W G; AcuPulse DUO
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 6, 2018
Received: March 6, 2018

Dear Amaya De Levie:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180597

Device Name

The Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO)

Indications for Use *(Describe)*

Intended Use/ Indications for Use:

The Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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:
- Keratosis, including actinic and seborrheic keratosis, seborrhoea 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
- 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 or coagulation of:
- Benign/malignant vascular/avascular skin lesions
- Moh's surgery
- Lipectomy
- Verrucae and seborrhoecae vulgares, including paronychial, periungal 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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, periungal 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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)
• 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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
• Pilonidal cyst removal and repair
• Abscesses
• Other soft tissue applications

Dental and Oral Surgery
The Lumenis AcuPulse Family of CO2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

The Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories

Applicant Name: Lumenis Ltd.
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Date Prepared: 06 March 2018

Trade Name: Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO)

Classification Name: Powered laser surgical instrument

Product Code: GEX

Device Class: Class II

Regulation Number: 21 C.F.R. § 878.4810

Panel: General & Plastic Surgery

Predicate Device: AcuPulse 30/40ST and AcuPulse 40WG CO_2 Lasers (K100415)

Intended Use/ Indications for Use:

The Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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:
  - Keratosis, including actinic and seborrheic keratosis, seborrhoea 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
  - 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 or coagulation of:
  - Benign/malignant vascular/avascular skin lesions
  - Moh's surgery
  - Lipectomy
  - Verrucae and seborrhoecae vulgares, including paronychial, periungal 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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, periungal 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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)
- 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), 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 Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

Dental and Oral Surgery

The Lumenis AcuPulse Family of CO_2 Laser Systems, Delivery Devices and Accessories (AcuPulse, AcuPulse 40WG and AcuPulse DUO), is indicated 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

Device Description / Summary of Technological Characteristics:

The Lumenis AcuPulse Family of CO_2 Laser Systems are advanced computer-controlled Carbon Dioxide (CO_2) laser systems based on a DC-excited sealed-off CO_2 laser tube, that depending on their configuration, can provide up to 30 or 40-Watts on tissue. The AcuPulse Family of CO_2 Lasers includes the following system models:

- The AcuPulse (previously called AcuPulse 30/40ST) system that incorporates a Free Beam Port only.
- The AcuPulse 40WG System that incorporates a Fiber Port only.
- The AcuPulse DUO, a new member of the family, which incorporates both a Free Beam Port and a Fiber Port.

The AcuPulse DUO laser added to the AcuPulse family represents a combination of the previously cleared AcuPulse 30/40ST and AcuPulse 40WG lasers. The minor differences in technological characteristics between the AcuPulse DUO and the predicate systems exist to facilitate this integration (mechanical and software adaptations that enable having two ports in one System) and do not affect any of the device's functionalities or performance specifications. The AcuPulse DUO System, with the incorporation of both the Free Beam and the Fiber port in one console, shares the same underlying technology and fundamental functionality as the previously cleared AcuPulse Family of CO_2 Laser Systems. All of these laser systems are comprised of the following main functional components:

- a Laser Console with a port: a Free Beam Port to which an articulated arm is attached (AcuPulse model), a Fiber Port to which a Fiber is attached (AcuPulse 40WG), or both the Free Beam Port and Fiber Port (AcuPulse DUO)
- a Footswitch

- Various Free Beam Delivery Device and accessories (AcuPulse and AcuPulse DUO compatible) or Fiber Delivery Devices and accessories (AcuPulse 40WG and AcuPulse DUO compatible).

The AcuPulse DUO, similarly to the previously cleared AcuPulse and AcuPulse 40WG, is operated and controlled via proprietary software embedded in the Main controller, Peripheral controller units and PC.

The Delivery Devices and accessories, in accordance with their type and compatibility (e.g., Fiber Port or Free Beam port) are shared by all AcuPulse Laser Systems. The Free Beam Delivery Devices and accessories include: Endoscopes/Laparoscopy accessories, Handpieces/Tips, Micromanipulators, and Scanners with accessories and adaptors. The Fibers that may be used with the Fiber Port are supplied with various handpieces (through which the Fiber may be inserted for more convenient handling during surgical procedures) and additional accessories for Fiber maintenance and handling.[1]

Performance Data

Performance testing was conducted in order to demonstrate the performance of the modified AcuPulse Family of CO_2 Laser Systems, Delivery Devices, and Accessories and to verify that no different questions of safety and effectiveness have been raised due to the modifications introduced. The following activities were performed:

- Risk analysis (ISO 14971)
- Electrical and laser safety and electromagnetic compatibility testing as required to conform to recognized performance standards as follows:
    - AAMI/ANSI/IEC ES 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
    - IEC 60601-1-2: *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility- requirements and tests*
    - 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 the safety of diagnostic and therapeutic laser equipment.*
- Software verification and validation
- System testing demonstrating that the systems perform in compliance with their specifications and requirements

Test results indicated that the modified components of the AcuPulse Family of CO_2 Laser Systems, Delivery Devices, and Accessories perform in accordance with its requirements and specifications, which are derived from those of the cleared predicate device.

[1] The fiber accessories are cleared under K100384 and K130164

Conclusions

The modified AcuPulse Family of CO_2 Laser Systems, Delivery Devices, and Accessories are as safe and effective as the previously cleared predicate systems (K100415). The subject devices have the same intended use, indications for use, and principles of operation as the predicate devices, and the technological characteristics are nearly identical; the minor technological differences between the cleared and modified laser systems do not raise different questions of safety or effectiveness. In addition, performance data demonstrate that the modified devices perform as intended and comparably to the predicate devices. Thus, the modified AcuPulse Family of CO_2 Laser Systems, Delivery Devices, and Accessories are substantially equivalent.