October 19, 2021

Lumenis, Ltd.
Shlomit Segman
Regulatory Affairs Director
6 Hakidma Street PO Box 240
Yokneam, Yokneam 2069204
Israel

Re: K212703
Trade/Device Name: AcuPulse CO2 Laser System, Delivery Devices and Accessories
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: August 19, 2021
Received: August 26, 2021

Dear Shlomit Segman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212703

Device Name

The modified AcuPulse System (member of the Lumenis Family of AcuPulse CO2 Laser System, delivery Devices and Accessories)

Indications for Use *(Describe)*

The Lumenis modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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 modified AcuPulse CO2 Laser System, Delivery Devices and Accessories, 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

The Lumenis modified AcuPulse Laser System, Delivery Devices and Accessories when used in conjunction with FemTouch and FemX, is indicated for the vaporization, incision, excision, ablation and coagulation of body soft tissue in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopedics, general and thoracic surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

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)

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510(K) SUMMARY

The Lumenis Modified AcuPulse CO_2 Laser System, Delivery Devices and Accessories (member of the Lumenis Family of AcuPulse CO_2 Laser Systems, Delivery Devices and Accessories)

Applicant's Name:

Lumenis Ltd.
6 Hakidma Street PO Box 240
Yokneam Industrial Park,
Yokneam 2069204, Israel
Tel: +972-4-9599000
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Contact Person:

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Tel: +972-4-9599230
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Email: Shlomit.segman@lunmenis.com

Date Prepared: August 17, 2021

Trade Name: AcuPulse System (member of the Lumenis Family of AcuPulse CO_2 Laser System, delivery Devices and Accessories)

Classification Name: Powered laser surgical instrument (Product Code GEX)

Device Class: Class II

Regulation Number: 21 CFR 878.4810

Panel: General & Plastic Surgery

Predicate Device: AcuPulse System, member of the AcuPulse Family of CO_2 Lasers systems (K180597) and AcuPulse W (K201663 and K202428).

Intended Use/ Indications for Use:

The Lumenis AcuPulse CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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 CO_2 Laser System, Delivery Devices and Accessories, 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

The Lumenis AcuPulse Laser System, Delivery Devices and Accessories when used in conjunction with FemTouch and FemX, is indicated for the vaporization, incision, excision, ablation and coagulation of body soft tissue in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopedics, general and thoracic surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Device Description:

The Lumenis AcuPulse CO_2 Laser System is an advanced computer-controlled Carbon Dioxide (CO_2) laser system, based on a DC-excited sealed-off CO_2 laser tube, that can provide up to 30 or 40 Watts (depending on the configuration) on tissue. The AcuPulse CO_2 Laser system consists of the following main functional components:

- a Laser Console with a Free Beam Port, to which an articulated arm is attached
- a Footswitch to activate the laser treatment beam and allow the selected lase energy to be transmitted via the delivery device to the target location
- a variety of Free Beam Delivery Devices and accessories.

The Free Beam Delivery Devices and accessories include: Endoscopes/Laparoscopy accessories, Handpieces/Tips, Micromanipulators, and Scanners with accessories and adaptors and the FemTouch handpieces.

The modified AcuPulse system, similarly to its predicates, the previously cleared AcuPulse System (member of the cleared AcuPulse Family of CO_2 Laser Systems, cleared under K180597) and the Previously cleared AcuPulse W system (K201663 and K202428), is operated and controlled via proprietary software embedded in the Main controller, Peripheral controller units and PC.

The modified AcuPulse System, with the incorporation of the FemTouch and FemX handpieces, shares the same underlying technology and fundamental functionality as its predicates.

Substantial Equivalence

The intended use of the modified AcuPulse CO_2 laser System, delivery devices and accessories is the same as that of its predicates, the AcuPulse system (K180597) and the AcuPulse W system (K201663 and K202428), and is: vaporization, incision, excision, ablation or

photocoagulation of soft tissue. The specific indications are identical to those of the cleared AcuPulse System (K180597) with the addition of the general indications of the AcuPulse W (K201663 and K202428), when used with the FemTouch and FemX handpieces.

The introduced modifications, i.e. the addition of the FemTouch and FemX handpieces and the software update, do not affect the intended use or mode of operation of the system and do not raise any new question of safety and/or effectiveness. The system console and the rest of the accessories remain unchanged, i.e. no change was performed to the system console and system specifications, maintaining the identical technological characteristics and principle of operation as the cleared AcuPulse CO_2 laser System and AcuPulse W system, with their delivery devices and accessories.

Performance data:

Design verification processes were performed following a risk assessment, to verify that no different questions of safety and effectiveness have been raised due to the modifications introduced. The test methods are essentially the same as those used to support the clearance of the AcuPulse CO_2 laser System (K180597) and the AcuPulse W system (K201663 and K202428).

The following activities were performed:

- Risk analysis activities in compliance with the requirements of ISO 14971.
- Electrical and laser safety and electromagnetic compatibility testing, are based on those of the cleared predicates and as required to demonstrated that the addition of the accessory (FemX handpiece) does not affect the compatibility with the requirements of the IEC 60601-1, IEC 60601-2-22, IEC 60825-1 and IEC 60601-1-2 standards.
- Where applicable, verification of risk mitigations for the FemX handpiece are based on tests performed with the 90° Side-firing Handpiece (FemTouch), which is considered equivalent. In other cases, performance tests were performed with the FemX handpiece, similarly as performed for the predicates in K180597, K201663 and K202428. Testing demonstrating that the system performs in compliance with its specifications and requirements.
- Compatibility of the 90° Side-firing Handpiece (FemTouch) with the predicate AcuPulse W system was demonstrated in both K201663 and K202428 and is applicable to the AcuPulse system.
- The biocompatibility of the introduced reusable and disposable parts of the FemTouch (previously cleared under K201663 and K202428) and FemX handpieces was evaluated, based on available data. It was concluded that the materials in contact with the human body, identical to materials present in cleared predicate accessories (K100415, K201663 and K202428), comply with ISO 10993-1 and FDA's guidance, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process"
- Cleaning, disinfection and sterilization, as well as shelf-life validation of the introduced reusable and disposable parts of the FemTouch and FemX handpieces were evaluated according to their instructions for use and are based on data submitted in prior submissions (mainly K201663 and K202428).

- Software verification and validation testing was conducted in order to evaluate the performance of the modified AcuPulse CO_2 Lasers System, Delivery Devices and Accessories, and to verify that it performs according to its specifications as described in the Software Test and Design documents.

Test results indicated that the modified AcuPulse CO_2 Laser System, Delivery Devices and Accessories, performs in accordance with its requirements and specifications, which are the same as those of the cleared predicates devices. Consequently, Lumenis Ltd. Believes that the modified AcuPulse CO_2 Laser System, Delivery Devices and Accessories, is substantially equivalent to its cleared predicates and the modifications do not affect the device's intended use nor alter the device's fundamental scientific technology and do not raise any new questions of safety and effectiveness.