December 24, 2020

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

Re: K203544
Trade/Device Name: UltraPulse Surgical and Aesthetic 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: November 25, 2020
Received: December 4, 2020

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*

K203544

Device Name
UltraPulse Surgical and Aesthetic CO2 Laser System, Delivery Devices, and Accessories

Indications for Use *(Describe)*

The UltraPulse system (UltraPulse and UltraPulse DUO models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO2 Surgical Lasers) is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.
The UltraPulse system (UltraPulse and UltraPulse DUO models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO2 Surgical Lasers) is indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery as follows:

Dermatology & Plastic Surgery

-The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:
• Laser skin resurfacing
• Laser derm-abrasion
• Laser burn debridement

-Laser skin resurfacing (ablation and/or vaporization) for 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
• 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 and 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

-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
• 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 matrixectomy

Otolaryngology (ENT)

-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 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

Gynecology (GYN)

-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 Bowen's disease (Erythrolasia of Queyrat) and Bowenoid papulosa (BP) lesions
• Leukoplakia (vulvar dystrophies)
• Incision and drainage (I&D) of Bartholin's and nubuthian cysts
• Herpes vaporization
• Urethral caruncle vaporization
• Cervical dysplasia
• Benign and malignant tumors
• Hemangiomas

GYN Laparoscopy

-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/ovariectomy
• Fimbrioplasty
• Metroplasty
• Microsurgery (tubal)
• Uterine myomas and fibroids
• Ovarian fibromas and follicle cysts
• Uterosacral ligament ablation
• Hysterectomy

Neurosurgery

-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

-Incision/excision and vaporization of soft tissue in orthopedic surgery, including the following applications:
• Arthroscopy
• Menisectomy
• 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

-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

-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

Genitourinary
-Incision/excision and vaporization of soft tissue in genitourinary procedures. Applications include:
• Benign and malignant lesions of external genitalia
• Condyloma
• Phimosis
• Erythroplasia

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 Modified UltraPulse System (member of the Lumenis Family of UltraPulse SurgiTouch $CO_2$ Surgical and Aesthetic Lasers, Delivery Devices and Accessories)


| | |
|---|---|
| Applicant Name: | Lumenis Ltd.<br>6 Hakidma Street PO Box 240<br>Yokneam Industrial Park,<br>Yokneam 2069204, Israel<br>Tel: +972-4-9599000<br>Fax: +972-4-9599046 |
| Contact Person: | Shlomit Segman Lumenis Ltd.<br>6 Hakidma Street PO Box 240,<br>Yokneam Industrial Park,<br>Yokneam 2069204, Israel<br>Tel: +972-4-9599230<br>Fax: +972-4-9599198<br>Email:Shlomit.Segman@lumenis.com |
| Date Prepared: | 25 November 2020 |
| Trade Name: | The modified UltraPulse System (member of the Lumenis Family of UltraPulse SurgiTouch $CO_2$ Surgical and Aesthetic Lasers, Delivery Devices and Accessories) |
| Classification | Powered laser surgical instrument |
| Name: Product | GEX |
| Code: Device Class: | Class II |
| Regulation Number: | 21 CFR 878.4810 |
| Panel: | General & Plastic Surgery |
| Predicate Devices: | Lumenis Family of UltraPulse SurgiTouch $CO_2$ Lasers, Delivery Devices and Accessories, recently cleared under K151331. |
| Reference Devices: | Previous Versions of Subject: K951812 K912029, K963339, K030147 |


**Intended Use/ Indications for Use:**

The modified UltraPulse $CO_2$ Laser System, Delivery Devices and Accessories shares with its predicate exactly the same intended use. Accordingly, the Indications for Use statement of the modified subject system, as presented below, is identical to the statement cleared under K151331.

The modified UltraPulse System, subject of this submission as well as its cleared UltraPulse SurgiTouch Family of $CO_2$ Aesthetic and Surgical Laser systems (UltraPulse SurgiTouch, UltraPulse Encore, UltraPulse and UltraPulse DUO members), Delivery Devices and Accessories are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The modified UltraPulse model, subject of this submission as well as its cleared UltraPulse SurgiTouch Family of Surgical and Aesthetic $CO_2$ Laser systems (UltraPulse SurgiTouch, UltraPulse Encore, and UltraPulse DUO members), Delivery Devices and Accessories are indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery as follows:

**Dermatology & Plastic Surgery**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Laser derm-abrasion
- Laser burn debridement

Laser skin resurfacing (ablation and/or vaporization) for 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
- 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 and 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**

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
- 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 matrixectomy

**Otolaryngology (ENT)**

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 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

**Gynecology (GYN)**

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 Bowen's disease (Erythrolasia of Queyrat) and Bowenoid papulosa (BP) lesions
- Leukoplakia (vulvar dystrophies)
- Incision and drainage (I&D) of Bartholin's and nubuthian cysts
- Herpes vaporization
- Urethral caruncle vaporization
- Cervical dysplasia
- Benign and malignant tumors
- Hemangiomas

**GYN Laparoscopy**

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/ovariectomy
- Fimbrioplasty
- Metroplasty
- Microsurgery (tubal)
- Uterine myomas and fibroids
- Ovarian fibromas and follicle cysts
- Uterosacral ligament ablation
- Hysterectomy

**Neurosurgery**

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**

Incision/excision and vaporization of soft tissue in orthopedic surgery, including the following applications:

- Arthroscopy
- Menisectomy
- 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**

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**

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

**Genitourinary**

Incision/excision and vaporization of soft tissue in genitourinary procedures. Applications include:

- Benign and malignant lesions of external genitalia
- Condyloma
- Phimosis
- Erythroplasia

**Device Description:**

The modified UltraPulse System, member of the UltraPulse SurgiTouch Family of $CO_2$ Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories (K951812 K912029, K963339 K030147 and K151331), is a carbon dioxide laser system based on a Radio Frequency (RF) modulated $CO_2$ laser tube.

The modified UltraPulse is based on the following hardware components in the Lumenis Family of UltraPulse $CO_2$ Laser System, Delivery Devices and Accessories:

- 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 laser energy to be transmitted via the delivery device to the target location.
- A variety of Free Beam Delivery Device and accessories

The modified UltraPulse, similarly to the recent members of the cleared Lumenis Family of UltraPulse $CO_2$ Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories (UltraPulse and UltraPulse DUO models) has a similar proprietary software, which is embedded in the Main Controller, Peripheral Controller units and PC.

The modified UltraPulse $CO_2$ Laser System, is a version of the cleared Lumenis Family of UltraPulse $CO_2$ Laser System, Delivery Devices and Accessories (see K030147 and K151331 for the latest clearances) with modifications to meet the marketing requirements for a new system with a subset of the supported aesthetic and surgical scanners and accessories. The modified UltraPulse System now supports the Aesthetic Scanners, UltraScan CPG and DeepFX Microscanner used with the cleared UltraPulse SurgiTouch/Encore Systems but with a modern GUI, PC and Operating System. In addition, other hardware, electronic and Software changes were introduced to replace obsolete components. The proposed system relies on the same fundamental underlying technology of the cleared systems with some modifications as compared to the cleared family members.

In addition, this submission describes several minor post-clearance modifications to the cleared Lumenis Family of Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories that were the subject of contemporary regulatory analyses that determined that changes could not significantly affect safety or effectiveness. Accordingly, these post-clearance modifications were implemented via internal documentation and no pre-marketing submission was filed. The post-clearance modifications, include addition of the modified SurgiTouch Scanner (cleared under K951812 and K022060), called the DeepFX Microscanner to the UltraPulse SurgiTouch/Encore system, almost identical to the AcuScan120 Microscanner cleared with the Lumenis AcuPulse $CO_2$ Laser system (K100415). Modernization of electronics and hardware of all systems to replace outdated parts and to meet new contemporary standards (e.g., IEC 60601-1-2 Ed.4, IEC 60601-1 Ed 3.1), improvements in laser calibration and stability and finally minor software modifications to enhance the user workflow and accessories supported (e.g., addition of treatment Preference and Utilities Screens and Training Videos).

**Substantial Equivalence**

The modified UltraPulse System, subject of this submission, is a modification of the Lumenis UltraPulse System (member of the UltraPulse SurgiTouch Family $CO_2$ Lasers Systems, Delivery Devices and Accessories) cleared under K151331. It is regarded as a modified member to the UltraPulse SurgiTouch $CO_2$ Laser family, Delivery Devices and Accessories. As such it shares with the cleared family members, the same intended use and underlying technology. The modifications introduced to the subject UltraPulse System as compared to its cleared family are designed and intended mainly for system modernization and increased user convenience in accordance with market/design inputs.

Design verification and validation processes were performed as a result of this risk analysis assessment to verify that no different questions of safety and effectiveness have been raised due to the modifications to this system. The test methods are essentially the same as those used to support to the clearance of the Family of UltraPulse SurgiTouch $CO_2$ Lasers and other Lumenis $CO_2$ laser systems (see K030147 and K151331 for the latest clearances).

The following activities were performed:

- Risk analysis per ISO 14971
- Electrical, laser and electromagnetic compatibility safety testing according to IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22 and IEC 60825-1
- Software verification and validation according to IEC 62304 and FDA Guidance "Principles of Software Validation Guidance for Industry and FDA Staff, January 2002".
- System testing (e.g., energy measurements, safety controls, emission indicator, scanners, aiming beam).
- Usability assessment to ensure that the usability of the modified system was not affected according to FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices, February 2016" , IEC 62366-1 and IEC 60601-1-6.
- As part of the Design Controls, the changes performed to the accessories since their clearance were evaluated. Reprocessing evaluation according to ISO 17665-1 and FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling FDA Guidance (2015, Updated June 9, 2017)". Biocompatibility evaluation according to ISO 10993-1 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process, September 2020". To date, no significant change in contact materials and processes of the Delivery Devices and accessories were performed since their clearance and/or release. Also no changes were performed in the contact parts and processes in order to work with the modified UltraPulse System, therefore it was concluded that no biocompatibility issues are raised and the biocompatibility data submitted in the previous 510(k) notices remains applicable to the modified device described in this submission.

Test results indicated that the modified UltraPulse performs in accordance with its requirements and specifications similarly to its predicate UltraPulse System member of the Lumenis Family of UltraPulse SurgiTouch $CO_2$ Surgical and Aesthetic Laser Systems. Consequently, Lumenis Ltd. believes that the modified UltraPulse $CO_2$ Laser System, Delivery Devices and Accessories is substantially equivalent to the cleared predicate and it does not raise any different questions of safety and/or effectiveness.