



Food and Drug Administration
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June 30, 2015

Lumenis Ltd.
Ms. Elissa Burg
Quality Assurance & Regulatory Affairs Director
6 Hakidma Street, P.O. Box 240
Yokneam Industrial Park
Yokneam 2069204
ISRAEL

Re: K151331

Trade/Device Name: The UltraPulse system (UltraPulse and UltraPulse DUO models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO2 Surgical Lasers)

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: May 31, 2015

Received: June 3, 2015

Dear Ms. Burg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -S

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

510(k) Number (if known)

K151331

Device Name

The UltraPulse system (UltraPulse and UltraPulse DUO models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO2 Surgical Lasers)

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 seborrhoeae vulgares, including paronychia, 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 paronychia, 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 neoplasia) and tonsil ablation/tonsillotomy
- Pulmonary bronchial and tracheal lesion removal

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- 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 (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 (Erythroplasia 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
- 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

-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)

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

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510(k) SUMMARY



UltraPulse system (UltraPulse and UltraPulse DUO models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers)

Applicant Name: Lumenis Ltd.
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Date Prepared: 13 May 2015

Trade Name: UltraPulse System (UltraPulse and UltraPulse DUO models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers)

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: Lumenis Family of UltraPulse SurgiTouch CO₂ Lasers, Delivery Devices and Accessories, cleared under K030147

Intended Use/ Indications for Use:

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, periungual, and subungual warts

Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

Laser ablation, vaporization, and/or excision of soft tissue for the reduction, removal, and/or treatment of:

- Verrucae vulgares/plantar (warts), including paronychial, periungual and subungual warts
- 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 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 (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 (Erythroplasia 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 UltraPulse System, subject of this submission, is a carbon dioxide laser system based on a Radio Frequency (RF) modulated CO₂ laser tube. It is a new member of the UltraPulse SurgiTouch Family of CO₂ Laser Systems, Delivery Devices and Accessories, previously cleared under K030147 and manufactured by Lumenis. The UltraPulse System relies on the same fundamental underlying technology of the cleared systems with some modifications as compared to the cleared family members.

The UltraPulse System, subject of this submission, includes two models: the UltraPulse and the UltraPulse DUO. The UltraPulse model delivers laser energy via a Free Beam Port to which an articulated arm and accessories are connected, similarly to the cleared UltraPulse SurgiTouch CO₂ Laser Systems (K030147). The UltraPulse DUO model incorporates also a Fiber Port to which a Fiber and accessories are connected, in addition to the Free Beam Port.

Both models of the UltraPulse System, subject of this submission, as well as its cleared UltraPulse SurgiTouch family (K030147), are comprised of the following main components:

- a Laser Console with a Free Beam Port to which a counterbalanced articulated arm is attached
- a Footswitch or Handswitch
- a variety of Delivery Device accessories or handpieces, including a scanning pattern generator

The UltraPulse DUO model includes also the following functional elements:

- a Fiber Port (on the Laser Console) to which a Fiber is attached
- a variety of Delivery Device accessories or handpieces, including a Fiber Support Arm and Fiber Handpiece Support Arm

The UltraPulse System (both models) is operated and controlled via proprietary SW embedded in the Main controller, Peripheral controller units and PC.

Substantial Equivalence

The UltraPulse System (both UltraPulse and UltraPulse DUO models), subject of this submission, is a modification of the Lumenis Family of UltraPulse SurgiTouch CO₂ Lasers cleared under K030147. Both UltraPulse models are regarded as additional members to the UltraPulse SurgiTouch CO₂ Laser family, Delivery Devices and Accessories. As such they share 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.

Performance testing was conducted in order to demonstrate the performance of the UltraPulse System (both models) and its substantial equivalence, with respect to safety and effectiveness, to the cleared predicate system. The following activities were performed:

- Risk analysis
- Electrical and laser safety and electromagnetic compatibility testing as required to conform to performance standards as follows:
 - EN 60825-1: Safety of laser products-Part 1: Equipment classification and requirements
 - EN 60601-2-22: Medical electrical equipment- part 2: particular requirements for the safety of diagnostic and therapeutic laser equipment.
 - EN 60601-1: Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance
 - EN 60601-1-2: Medical electrical equipment – Part 1-2 : General requirements for basic safety and essential performance- Collateral standard : Electromagnetic compatibility- requirements and tests
- Software verification and validation
- Ability of the subject system to withstand variant operation, storage and transportation conditions
- System testing (e.g., energy measurements, safety controls, emission indicator, DUO switching model, Fiber and Free Beam ports, scanner, aiming beam)

Test results indicated that the subject UltraPulse System (both models) performs in accordance with its requirements and specifications, in similarity to its predicate device. Consequently, the UltraPulse System (both models) was found to perform as well as its predicate, to be as safe and effective for its intended use as its predicate, and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.