DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2014

LightScalpel® LLC
Mr. David Walters
General Manager
16932 Woodinville-Redmond Road Northeast, Suite 107
Woodinville, Washington 98072

Re: K141658
Trade/Device Name: LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems
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 26, 2014
Received: August 28, 2014

Dear Mr. Walters:

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,

David Krause -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

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)*
K141658

Device Name

LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems

Indications for Use *(Describe)*

Indications for Use:
The LightScalpel LS-1005 & LS-2010 CO2 Laser Systems are intended for use in laser surgery procedures for incision, excision, vaporization, ablation, and/or coagulation of soft tissue in specialties such as: general surgery, dermatology, gynecology, dentistry and oral surgery, otorhinolaryngology, plastic and reconstructive surgery, orthopedic surgery, neurosurgery, podiatry, and urology.

Gynecology / Genitourinary:
Incision, excision, ablation, and/or vaporization of soft tissue for treatment of: Conization of the cervix, including cervical intraepithelial neoplasia and vulvar and vaginal intraepithelial neoplasia; Condyloma, including cervical, genital, vulvar, perineal, and Bowenoid papulosa; leukoplakia (vulvar dystrophies); incision and drainage of Bartholin's and nabothian cysts; herpes vaporization; urethral caruncle vaporization; cervical dysplasia; benign and malignant tumors; hemangiomas; 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) Number *(if known)*
K141658

Device Name

LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems

Indications for Use *(Describe)*

Dermatology / Plastic Surgery:
Incision, Excision, Ablation, and Vaporization of soft tissue for performance of or treatment of: laser skin resurfacing; laser dermabrasion; laser burn debridement; wrinkles, rhytids, and furrows; keratosis, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci 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 telagiectaticum; tattoos; telangiectasias; 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 & 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; complete or partial nail matrixectomy; benign/malignant vascular/avascular skin lesions; Mohs surgery; lipectomy; verrucae and seborrhoecae vulgares, including: paronychial, periungal, and subungual warts; blepharoplasty; and hair transplantation site preparation.

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

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Device Name

LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems

Indications for Use *(Describe)*

Dental Surgery:
Gingivectomy – Removal of hyperplasias; gingivoplasty; papillectomy; vestibuloplasty; epulis; sulcular debridement; removal of soft tissue, cysts, and fibroma (non-malignant tumor, mucosa, tongue); extraction site hemostasis; treatment of ulcerous lesions, including aphthous ulcers; a heat source to activate tooth bleaching materials; Laser Assisted New Attachment Procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium).

Oral Surgery:
Frenum release/frenectomy; abscess (drainage); flap surgery; biopsy (incisional & excisional); aphthous ulcers (incision & excision); excision & ablation of lesions, benign & malignant lesions, oral cavity tumors, and hemangiomas; salivary gland pathologies; preprosthetic gum preparation, leukoplakia; partial glossectomy; periodontal gum resection; homeostasis; operculectomy; crown lengthening (soft tissue); incision of infection when used with antibiotic therapy; extraction site hemostasis.

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

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510(k) Number *(if known)*
K141658

Device Name

LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems

Indications for Use *(Describe)*

General and Thoracic Surgery:
Incision, excision, and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures for: 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 and pilar cysts, and mucous cysts of the lips; pilonidal cyst removal and repair; abscesses; other soft tissue applications.

Gyn Laparoscopic Surgery:
Laser incision, excision, vaporization, and photocoagulation of soft tissue for treatment of: endometrial lesions, including ablation for endometriosis; excision/lysis of adhesions; salpingotomy; oophorectomy/ovariectomy; fimbrioplasty; metroplasty; uterine myomas and fibroids; ovarian fibromas and follicle cysts; uterosacral ligament ablation; hysterectomy.

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

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510(k) Number *(if known)*
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Device Name

LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems

Indications for Use *(Describe)*

Otorhinolaryngology / ENT:

Laser incision, excision, ablation, vaporization, and / or photocoagulation of soft tissue in otorhinolaryngology for treatment of: leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue; adult and juvenile papillomatosis polyps; lymphangioma removal; 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; stenosis, including subglottic stenosis; tonsillectomy (including tonsillar cryptolysis and neoplasma) and tonsil ablation / tonsillotomy; benign and malignant tumors and fibromas (oral); superficial lesions of the ear, including chondrodermatitis nondularis chronica helices / Winkler's disease; 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

Podiatry:

Laser excision, ablation, and /or vaporization of soft tissue in podiatry for the reduction, removal and/or treatment of: Verrucae vulgares / plantar warts, including paronychial, periungual, and subungual warts; fungal nail treatment; matrixectomy – partial and complete; porokeratoma ablation; neuromas/fibromas, including Morton's neuroma removal; ingrown toenail treatment; debridement of ulcers; treatment of other soft tissue lesions.

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

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510(k) Number *(if known)*
K141658

Device Name

LightScalpel® LS-1005 & LS-2010 CO2 Laser Systems

Indications for Use *(Describe)*

Orthopedic Surgery:
Laser incision / excision, ablation, and /or vaporization of soft tissue in orthopedic surgery. Applications include: meniscectomy; chondromalacia ablation; chondroplasty; ligament release (lateral and other); excision of plica; partial synovectomy; debridement of traumatic wounds; debridement of decubitus & diabetic ulcers; and PMMA removal.

Neurosurgery:
Laser incision / excision, ablation, and /or vaporization of soft tissue in neurosurgery for the treatment of: posterior fossa tumors; peripheral neurectomy; benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors); arteriovenous malformation; and pituitary gland tumors (transphenoidal approach).

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

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K141658

VOL_006 - 510(k) Summary

510(k) Summary Preparation Date: 17 June 2014

1. 510(K) Owner:
   LightScalpel® LLC
   16932 Woodinville-Redmond Road NE, Suite 107
   Woodinville, WA 98072
   866-697-7548 / 425-368-1588 / 425-368-1568 (FAX)

2. 510(k) Contact:
   David Walters
   General Manager
   16932 Woodinville-Redmond Road NE, Suite 107
   Woodinville, WA 98072
   866-697-7548 / 425-368-1588 / 425-368-1568 (FAX)
   dwalters@lightscalpel.com

3. Device Trade Name: LightScalpel® LS-1005 / LS-2010

   Common Name: CO_2 Laser System

   Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810).

   "A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide."

   Classification: Class II

   Product Code: GEX

4. Predicate Device(s):

   4.1. LightScalpel LS-1005 CO_2 Laser System; K123037 & K132661

   4.2. Alma Pixel CO_2™ Laser System; K103501

   4.3. Lumenis AcuPulse™ 30/40 ST & 40WG CO_2 Laser Systems; K100415

   4.4. Sharplan 15F CO_2 Laser System; K971743

5. Device Description and Function

The LightScalpel LS-1005 / LS-2010 laser systems are mobile platforms that utilizes a radio frequency (RF) excited carbon dioxide (CO_2) laser tube to produce an infrared beam at a nominal 10.6 µm wavelength at powers adjustable from 2 to 10 and 2 to 20 Watts Continuous Wave (CW) respectively. The systems differ only in the laser tube used, pre-programmed values in the controlling software, which allow higher laser tube drive for the LS-2010 system, and physical height and weight. Laser energy is conducted to the point of application by a flexible fiber waveguide and handpiece assembly. Laser system operation is controlled by operator input on a touch-screen display panel. The RF laser drive is modulated to provide additional pulsed and superpulse emission modes selected from the laser system control panel.

A “calibration port” on the side of the laser systems allows checking and setting the power emitted from the distal laser aperture to the internal power meter and serves as a check on fiber waveguide transmission efficiency. Laser system power, rates, and durations are adjustable as tabulated below:

The laser systems have safety features complying with requirements in 21 CFR 1040, Performance Standards for Light Emitting Products.

Primary safety features are as follows:
System On-Off Keyswitch, Emergency Stop Switch, Remote Interlock, Fiber Interlock, Beam Blocking Shutter, Internal Laser Power Detector, RF Power Monitor, and required Laser Safety Labels and Labeling.

Laser system physical characteristics are:
Delivery System: Flexible Fiber Waveguide; ~ 0.75mm ID.; Handpieces with internal focusing lens (“tipless”) and with disposable pre-sterilized ceramic tips.
Purge Gas: Internal air pump purge through the Fiber and Handpiece.
System Cooling: Air; two thermostatically controlled fans with over-temperature protection.
Mobility: 4 wheels and handgrip on console for convenient system positioning.

6. Intended use(s) of the Device

The LightScalpel CO_2 Laser Systems are intended for use in laser surgery procedures for incision, excision, vaporization, ablation, and/or coagulation of soft tissue in specialties such as: general surgery, dermatology, gynecology, dentistry and oral surgery, otorhinolaryngology, plastic and reconstructive surgery, orthopedic surgery, neurosurgery, podiatry, and urology.

A listing of typical laser surgery procedures in the medical specialties follows:

Gynecology / Genitourinary:

Incision, excision, ablation, and/or vaporization of soft tissue for treatment of:: Conization of the cervix, including cervical intraepithelial neoplasia and vulvar and vaginal intraepithelial neoplasia; Condyloma, including cervical, genital, vulvar, perineal, and Bowenoid papulosa; leukoplakia (vulvar dystrophies); incision and drainage of Bartholin's and nabothian cysts; herpes vaporization; urethral caruncle vaporization; cervical dysplasia; benign and malignant tumors; hemangiomas;; benign and malignant lesions of external genitalia; condyloma; phimosis; erythoplasia.

Dermatology / Plastic Surgery:

Incision, Excision, Ablation, and Vaporization of soft tissue for performance of or treatment of: laser skin resurfacing; laser dermabrasion; laser burn debridement; wrinkles, rhytids, and furrows; keratosis, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci 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 telagiectaticum; tatoos; telangiectasias; 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 & 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-epitheliazation; tricoepitheliomas; xanthelasma palpebrarum; syringoma; complete or partial nail matrixectomy; benign/malignant vascular/avascular skin lesions; Mohs surgery; lipectomy; verrucae and seborrhoecae vulgares, including: paronychial, periungal, and subungual warts; blepharoplasty; and hair transplantation site preparation.

Dental Surgery:

Gingivectomy – Removal of hyperplasias; gingivoplasty; papillectomy; vestibuloplasty; epulis; sulcular debridement; removal of soft tissue, cysts, and fibroma (non-malignant tumor, mucosa, tongue); extraction site hemostasis; treatment of ulcerous lesions, including aphthous ulcers; a heat source to activate tooth bleaching materials; Laser Assisted New Attachment Procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium).

Oral Surgery:

Frenum release/frenectomy; abscess (drainage); flap surgery; biopsy (incisional & excisional); aphthous ulcers (incision & excision); excision & ablation of lesions, benign & malignant lesions, oral cavity tumors, and hemangiomas; salivary gland pathologies; preprosthetic gum preparation, leukoplakia; partial glossectomy; periodontal gum resection; homeostasis; operculectomy; crown lengthening (soft tissue); incision of infection when used with antibiotic therapy; extraction site hemostasis.

General and Thoracic Surgery:

Incision, excision, and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures for: 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;
midiastinal and thoracic lesions and abnormalities; skin tag vaporization; atheroma; cysts, including sebaceous and pilar cysts, and mucous cysts of the lips; pilonidal cyst removal and repair; abscesses; other soft tissue applications.

Gyn Laparoscopic Surgery:

Laser incision, excision, vaporization, and photocoagulation of soft tissue for treatment of: endometrial lesions, including ablation for endometriosis; excision/lysis of adhesions; salpingotomy; oophorectomy/ovariectomy; fimbrioplasty; metroplasty; uterine myomas and fibroids; ovarian fibromas and follicle cysts; uterosacral ligament ablation; hysterectomy.

Otorhinolaryngology / ENT:

Laser incision, excision, ablation, vaporization, and / or photocoagulation of soft tissue in otorhinolaryngology for treatment of: leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue; adult and juvenile papillomatosis polyps; lymphangioma removal; 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; stenosis, including subglottic stenosis; tonsillectomy (including tonsilar cryptolysis and neoplasma) and tonsil ablation / tonsillotomy; benign and malignant tumors and fibromas (oral); superficial lesions of the ear, including chondrodermatitis nondularis chronica helices / Winkler's disease; 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

Podiatry:

Laser excision, ablation, and /or vaporization of soft tissue in podiatry for the reduction, removal and/or treatment of: Verrucae vulgares / plantar warts, including paronychial, periungal, and subungual warts; fungal nail treatment; matrixectomy – partial and complete; porokeratoma ablation; neuromas/fibromas, including Morton's neuroma removal; ingrown toenail treatment; debridement of ulcers; treatment of other soft tissue lesions.

Orthopedic Surgery:

Laser incision / excision, ablation, and /or vaporization of soft tissue in orthopedic surgery. Applications include: menisectomy; chondromalacia ablation; chondroplasty; ligament release (lateral and other); excision of plica; partial synovectomy; debridement of traumatic wounds; debridement of decubitus & diabetic ulcers; and PMMA removal.

Neurosurgery:

Laser incision / excision, ablation, and /or vaporization of soft tissue in neurosurgery for the treatment of: posterior fossa tumors; peripheral neurectomy; benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lopomas, and large tumors); arteriovenous malformation; and pituitary gland tumors (transphenoidal approach).

7. Technological Characteristics Comparison to Predicate Devices

The technological characteristics comparison to predicate devices is summarized in the following table.

	LS-1005 / LS-2010 K141658	**LS-1005 K123037 K132661**	**Alma Pixel CO_2™ K103501**	**Lumenis AcuPulse™ K100415**	**Sharplan 15F K971743**
Characteristic	--	--	--	--	--
Laser Medium	CO_2	CO_2	CO_2	CO_2	CO_2
Wavelength (µm)	10.6	10.6	10.6	10.6	10.6
Laser Drive Source	RF	RF	RF	DC	DC
Output Power (W)	2-10 / 2-20	2-10	70	1 - 30	1 - 15
Pulsed Power (W)	2-10 / 2-20	2-10	--	1 - 25	N/A
Gated PW (ms)	5-500	5-500	10 – 1000	50 - 1000	100 – 1000
Gated Rep. Rate (pps)	1 or 2-20	1 or 2-20	1 - 100	1 - 100	Adj – On/Off
Superpulse (W)	2-5 / 2-10	2-5	--	.5 - 10	N/A
Superpulse Peak (W)	30 / 60	30	--	N/A	N/A
Beam Delivery System	Flexible Fiber Waveguide	Flexible Fiber Waveguide	Articulated Arm	Articulated Arm or WG	Articulated Arm/WG
System HxWxD (in)	34x15x15 / 40x15x15	34x15x15 / 40x15x15	52x17x21	47x15x16	4.3x9.4x28.3
System Weight (lb)	35 / 47	35 / 47	135	108	33
Mobility	4 Wheels & Handle	4 Wheels & Handle	4 Wheels & Handle	4 Wheels & Handle	4 Wheels & Handle
Intended Use	Incision, Excision, Vaporization, Ablation, and/or Coagulation of Soft Tissue	Incision, Excision, Vaporization, Ablation, and/or Coagulation of Soft Tissue	Incision, Excision, Vaporization, Ablation, and/or Coagulation of Soft Tissue	Incision, Excision, Vaporization, Ablation, and/or Coagulation of Soft Tissue	Incision Excision Vaporization Ablation And/or Coagulation of Soft Tissue
Line Voltage – Nom.	100-240 VAC	100-240 VAC	120/230 VAC	100-240 VAC	100-140 VAC

The LS-1005 and LS-2010 laser systems are substantially equivalent to the predicate devices in emission wavelength, control parameters, relative output power, delivery accessories, and physical size.

8. Non-clinical performance data: Each LS-1005 and LS-2010 laser system is tested for electrical safety and output characteristics. Representative data is presented in the Bench Testing section of this report.
9. Clinical performance data: None. Clinical testing was determined to be unnecessary, as the performance parameters are consistent with predicate CO_2 laser systems and technology.
10. In summary, the LightScalpel LS-1005 and LS-2010 CO_2 laser systems are equivalent to the predicate laser systems in technical characteristics and for the intended uses in the stated medical specialties.