



September 14, 2018

LightScalpel LLC  
David Walters  
General Manager  
11818 North Creek Parkway N  
Suite 100  
Bothell, Washington 98011

Re: K173827

Trade/Device Name: LightScalpel® LS 2010 SX, LS-2010 FX, and LS-2010 DX CO2 Laser System  
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 7, 2018  
Received: August 13, 2018

Dear David 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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

Sincerely,

**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

## Indications for Use

510(k) Number (if known)  
K173827

Device Name

LightScalpel® LS-2010 SX, LS-2010 FX, and LS-2010 DX CO2 Laser Systems

Indications for Use (Describe)

The LightScalpel LS-2010 SX, LS-2010 FX, and LS-2010 DX 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.

Intended uses specific to the LS-2010 FX and LS-2010 DX in fractional mode are indicated by \*\*.

Dermatology / Plastic Surgery:

Ablation, and Vaporization of soft tissue for performance of or treatment of: laser skin resurfacing; laser dermabrasion; laser burn debridement; wrinkles\*\*, rhytids\*\*, and furrows\*\*; textural irregularities\*\*; vascular dyschromia\*\*; and benign pigmented lesions\*\*

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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## Indications for Use

510(k) Number (if known)  
K173827

Device Name  
LightScalpel® LS-2010 SX, LS-2010 FX, and LS-2010 DX CO2 Laser Systems

### Indications for Use (Describe)

Intended uses specific to the LS-2010 SX and LS-2010 DX in surgical mode are listed below.

#### 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 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.

#### 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.

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

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Device Name

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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; textural irregularities; keratosis, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci wart, and verruca seborrheica; vermilionectomy of the lip; cutaneous horns; solar/actinic elastosis; cheilitis, including actinic cheilitis; lentigines, including lentigo maligna or Hutchinson's freckle; uneven pigmentation/vascular dyschromia;; surgical scars; keloids, including acne keloidalis nuchae; hemangiomas, including Buccal, port wine, and pyogenic granulomas/granuloma, pyogenicum/granuloma telangiectaticum; tattoos; telangiectasias; removal of small skin tumors, including periungual (Koenen) and subungual fibromas; benign 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 vascular/avascular skin lesions; Mohs surgery; lipectomy; verrucae and seborrhoecae vulgares, including: paronychial, periungual, and subungual warts; blepharoplasty; and hair transplantation site preparation.

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 tumors; hemangiomas; benign lesions of external genitalia; condyloma; phimosis; erythroplasia.

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

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510(k) Number (if known)  
K173827

Device Name

LightScalpel® LS-2010 SX, LS-2010 FX, and LS-2010 DX CO2 Laser Systems

Indications for Use (Describe)

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 tonsillar cryptolysis and neoplasia) and tonsil ablation / tonsillotomy; benign tumors and fibromas (oral); superficial lesions of the ear, including chondrodermatitis nodularis 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 paronychia, 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)  
K173827

Device Name  
LightScalpel® LS-2010 SX, LS-2010 FX, and LS-2010 DX 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 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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## **VOL\_007 - 510(k) Summary**

510(k) Summary Preparation Date: 13 September 2018

1. 510(K) Owner:  
 LightScalpel® LLC  
 11818 North Creek Parkway N, Suite 100  
 Bothell, WA 98011  
 866-697-7548 / 425-368-1588 / 425-368-1568 (FAX)
  
2. 510(k) Contact:  
 David Walters  
 General Manager  
 11818 North Creek Parkway N, Suite 100  
 Bothell, WA 98011  
 866-697-7548 / 425-368-1588 x472 / 425-368-1568 (FAX)  
 dwalters@lightscalpel.com
  
3. Device Trade Name: LightScalpel® LS-2010 SX, LS-2010 FX, and LS-2010 DX CO<sub>2</sub> Laser System  
 Common Name: CO<sub>2</sub> 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. Primary Predicate Device: LightScalpel LS-1005 / LS-2010 CO<sub>2</sub> Laser System; K141658
  - 4.2. Reference Predicate Device: Lutronic eCO<sub>2</sub>™ Laser System; K100610
  - 4.3. Reference Predicate Device: Lasering MiXto, K110984

## 5. Device Description and Function

The LightScalpel LS-2010 SX, LS-2010 FX, and LS-2010 DX laser systems are mobile platforms that utilize a radio frequency (RF) excited carbon dioxide (CO<sub>2</sub>) laser tube to produce an infrared beam at a nominal 10.6  $\mu$ m wavelength. Output parameters are summarized in Table 1. 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.

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 (7):

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:

LS-2010 SX, Flexible Fiber Waveguide; ~ 0.75mm ID, Handpieces with internal focusing lens (“tipless”) and with disposable pre-sterilized ceramic tips.

LS-2010 FX & DX; Flexible Fiber Waveguide; ~ 0.50mm ID, Handpiece with internal beam steering galvanometers and laser diode aiming beam.

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 LS-2010 SX, LS-2010 FX, and LS-2010 DX 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.

**Intended uses specific to the LS-2010 FX and LS-2010 DX in fractional mode are indicated by \*\*.**

### Dermatology / Plastic Surgery:

Ablation and Vaporization of soft tissue for performance of or treatment of: laser skin resurfacing; laser dermabrasion; laser burn debridement; wrinkles\*\*, rhytids\*\*, and furrows\*\*; textural irregularities\*\*; vascular dyschromia\*\*; and benign pigmented lesions\*\*;

**Intended uses specific to the LS-2010 SX and LS-2010 DX in surgical mode are listed below.**

### 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; textural irregularities; keratosis, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci wart, and verruca seborrheica; vermilionectomy of the lip; cutaneous horns; solar/actinic elastosis; cheilitis, including actinic cheilitis; lentigines, including lentigo maligna or Hutchinson's freckle; uneven pigmentation/vascular dyschromia; surgical scars; keloids, including acne keloidalis nuchae; hemangiomas, including Buccal, port wine, and pyogenic granulomas/granuloma, pyogenicum/granuloma telangiectaticum; tattoos; telangiectasias; removal of small skin tumors, including periungual (Koenen) and subungual fibromas; benign 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 vascular/avascular skin lesions; Mohs surgery; lipectomy; verrucae and seborrhoecae vulgares, including: paronychia, 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



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; 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.

#### 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 tumors; hemangiomas; benign lesions of external genitalia; condyloma; phimosis; erythroplasia.

#### 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 tonsillar cryptolysis and neoplasia) and tonsil ablation / tonsillotomy; benign tumors and fibromas (oral); superficial lesions of the ear, including chondrodermatitis nodularis 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 paronychia, 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 tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, 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.

**Table 1**

| Predicate 510(k)                         | LightScalpel<br>LS-2010 SX      | LightScalpel<br>LS-2010 FX                                                          | LightScalpel<br>LS-2010 DX                                                           | LightScalpel<br>LS-2010<br>K141658 | Lutronic<br>eCO2™<br>K100610                                                          | Lasering<br>MiXto<br>K110984                                                          |
|------------------------------------------|---------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Characteristic                           | --                              | --                                                                                  | --                                                                                   | --                                 | --                                                                                    | --                                                                                    |
| Laser Medium                             | CO2                             | CO2                                                                                 | CO2                                                                                  | CO2                                | CO2                                                                                   | CO2                                                                                   |
| Wavelength (µm)                          | 10.6                            | 10.6                                                                                | 10.6                                                                                 | 10.6                               | 10.6                                                                                  | 10.6                                                                                  |
| Laser Drive Source                       | RF                              | RF                                                                                  | RF                                                                                   | RF                                 | RF                                                                                    | DC                                                                                    |
| Energy Delivery – Cont. Wave (CW)        |                                 |                                                                                     |                                                                                      |                                    |                                                                                       |                                                                                       |
| Output Power (W)                         | 2-20                            | --                                                                                  | 2-20                                                                                 | 2-20                               | 30 Max                                                                                | 30 Max                                                                                |
| Pulsed Power (W)                         | 2-20                            | --                                                                                  | 2-20                                                                                 | 2-20                               | --                                                                                    | 5 - 25                                                                                |
| Gated PW (ms)                            | Single                          | 5-500                                                                               | --                                                                                   | 5-500                              | 10-1000                                                                               | 50 - 1000                                                                             |
|                                          | Repeat                          | 5-200                                                                               | --                                                                                   | 5-200                              |                                                                                       |                                                                                       |
| Gated Rep. Rate (pps)                    | 1 - 50                          | --                                                                                  | 1-50                                                                                 | 1-50                               | 1 - 550                                                                               | 1 - 100                                                                               |
| Single Pulse Energy (mJ)                 | 10-10000                        | --                                                                                  | 10-10000                                                                             | 10-10000                           | --                                                                                    | --                                                                                    |
| Energy Delivery – Superpulse (SP)        |                                 |                                                                                     |                                                                                      |                                    |                                                                                       |                                                                                       |
| Superpulse (W)                           | 2-10                            | --                                                                                  | 2-10                                                                                 | 2-10                               | --                                                                                    | .5 - 12                                                                               |
| Superpulse Peak (W)                      | 50                              | --                                                                                  | 50                                                                                   | 50                                 | --                                                                                    | --                                                                                    |
| Gated PW (ms)                            | Single                          | 10-500                                                                              | --                                                                                   | 10-500                             | 1-1000                                                                                | --                                                                                    |
|                                          | Repeat                          | 10-200                                                                              | --                                                                                   | 10-200                             | ---                                                                                   | --                                                                                    |
| SP Pulse Rates (pps)                     | 150-500                         | --                                                                                  | 150-500                                                                              | 150-500                            | --                                                                                    | --                                                                                    |
| SP Gated Rep Rates (pps)                 | 1-50                            | --                                                                                  | 1-50                                                                                 | 1-50                               | --                                                                                    | --                                                                                    |
| SP Pulse Width (µsec)                    | 100-800                         | --                                                                                  | 100-800                                                                              | 100-800                            | 1000-5000                                                                             | --                                                                                    |
| Energy Delivery - Scanner                |                                 |                                                                                     |                                                                                      |                                    |                                                                                       |                                                                                       |
| Pulse Duration (msec)                    | --                              | 0.1-6.6                                                                             | 0.1-6.6                                                                              | --                                 | 0.10-13.4                                                                             | 0.25-16                                                                               |
| Pulse Energy (mJoules)                   | --                              | 10-150                                                                              | 10-150                                                                               | --                                 | 2-240                                                                                 | 1-480                                                                                 |
| Energy Adjustability                     | --                              | 10 mJ Inc.                                                                          | 10 mJ Inc.                                                                           | --                                 | --                                                                                    | --                                                                                    |
| Pulse Frequency (Hz)                     | --                              | 75-150                                                                              | 75-150                                                                               | --                                 | 10-200                                                                                | --                                                                                    |
| Peak Power (W)                           | --                              | ~23                                                                                 | ~23                                                                                  | --                                 | 30                                                                                    | --                                                                                    |
| Radiation Scan Area (mm)                 | --                              | 5x5 – 10x10                                                                         | 5x5 – 10x10                                                                          | --                                 | 18x18                                                                                 | Up to 20x20                                                                           |
| Scan Shapes                              | --                              |  |  | --                                 |  |  |
| Beam Diameter (Fractional - mm)          | --                              | 0.25                                                                                | 0.25                                                                                 | --                                 | 0.12                                                                                  | 0.12 / 0.30                                                                           |
| Scan Density (%) (Ablative %)            | --                              | 5, 8, 14 (100)                                                                      | 5, 8, 14 (100)                                                                       | --                                 | 1 – 14                                                                                | 5 – 40 (100)                                                                          |
| Beam Density (spots/cm2)                 | --                              | 100 (5%), 144 (8%), 289 (14%)                                                       | 100 (5%), 144 (8%), 289 (14%)                                                        | --                                 | 25-400                                                                                | --                                                                                    |
| Inter-beam Spacing (mm)                  | --                              | 1mm (5%), 0.8mm (8%), 0.6mm (14%)                                                   | 1mm (5%), 0.8mm (8%), 0.6mm (14%)                                                    | --                                 | 0.7mm (14%)                                                                           | --                                                                                    |
| Visible Laser Indicator                  |                                 |                                                                                     |                                                                                      |                                    |                                                                                       |                                                                                       |
| Diode, 635-650nm, ≤ 5mw, Class IIIa / 3R | --                              | X                                                                                   | X                                                                                    | --                                 | X                                                                                     | X                                                                                     |
| Physical Specifications                  |                                 |                                                                                     |                                                                                      |                                    |                                                                                       |                                                                                       |
| Beam Delivery System                     | Flexible Fiber Waveguide        |                                                                                     |                                                                                      | Flexible Fiber Waveguide           | Articulated Arm                                                                       | Articulated Arm / WG                                                                  |
| System HxWxD (in)                        | 40x15x15                        |                                                                                     |                                                                                      | 40x15x15                           | 74x14x18                                                                              | 48x15x17                                                                              |
| System Weight (lb)                       | 47                              |                                                                                     |                                                                                      | 47                                 | 106                                                                                   | 88                                                                                    |
| Mobility                                 | 4 Wheels & Handle               |                                                                                     |                                                                                      | 4 Wheels & Handle                  | 4 Wheels & Handle                                                                     | 4 Wheels & Handle                                                                     |
| Electrical Specifications                |                                 |                                                                                     |                                                                                      |                                    |                                                                                       |                                                                                       |
| Input Voltage, Frequency, Amps           | 100-240VAC<br>50/60Hz<br>8A Max |                                                                                     |                                                                                      | 100-240VAC<br>50/60Hz<br>8A Max    | 100-240VAC<br>50/60Hz<br>600VA                                                        | 100-240VAC<br>50/60Hz<br>4A Max                                                       |



The LS-2010 Series 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-2010 Series laser system is tested for electrical safety and output characteristics. Representative data sheets are 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<sub>2</sub> laser systems and technology.
10. In summary, the LightScalpel LS-2010 SX, LS-2010 FX, and LS-2010 DX CO<sub>2</sub> laser systems are equivalent to the predicate laser systems for the indicated uses in the stated medical specialties.