LightScalpel® LLC
16932 Woodinville-Redmond Rd NE, Suite 107
Woodinville, WA 98072
PH: 425-368-1588 FAX: 425-368-1568

VOL_006 - 510(k) Summary 3

JAN - 2 2014

510(k) Summary Preparation Date: 27 November 2013.

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

   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)

   The LightScalpel LS-10 / LS-1005 CO_2 Laser System was previously cleared per K123037.

   Additional Indications for Use are equivalent to the following predicates:

   4.1 K081612, Aesculight / K121471, LightScalpel Laser Accessories

   4.2 K960475, Luxar LX20 CO_2 Laser System

   4.3 K091320, Lutronic Spectra DENTA II CO_2 Laser System

   4.4 K100416, Lumenis AcuPulse CO_2 Laser System

   4.5 K971743, Sharplan 15F CO_2 Laser System

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5. Device Description and Function

The LightScalpel LS-1005 laser system is a mobile platform 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 Watts Continuous Wave (CW). 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 system allows checking and setting the power emitted from the distal laser aperture and serves as a check on fiber waveguide transmission efficiency. Laser system power, rates, and durations are adjustable as tabulated below:

Parameter	LightScalpel LS-1005
CW Power (watts)	2 – 10
Pulsed Power (watts)	2 – 10
Gated Pulse Width (msec)	5 – 500
Gated Rep Rate (pps)	1 or 2 – 20
Single Pulse Energy (mJ)	10 - 5000
Superpulse Power (watts-avg.)	2 – 5
Gated Pulse Widths (msec)	10 – 500
Superpulse Pulse Rates (pps)	160 – 375
Gated Rep Rate (pps)	1 or 2 – 30
Superpulse Peak Power (watts)	30
Superpulse Pulse Width (µsec)	100 -800

The laser system has safety features complying with requirements in 21 CFR 1040, Performance Standards for Light Emitting Products; IEC 60601-2-22, Medical electrical equipment –Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment ; and IEC 60825-1, Safety of laser products –Part 1: Equipment classification and requirements. Major safety features are as follows:

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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.

The laser system, components, and features are illustrated in Figure 1. Laser system physical characteristics are:

Parameter	LightScalpel LS-10
Dimensions	40" H x 15" W x 15" D
Weight (Pounds / Kg)	~ 47 / ~ 21
Electrical Power	115 VAC, 7.5 A, 50/60 Hz

Delivery System: Flexible Fiber Waveguide; ~ 0.7mm 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 System is intended for use in laser surgery procedures for incision, excision, vaporization, ablation, or coagulation of soft tissue in specialties such as: general surgery, dermatology, gynecology, dentistry and oral surgery, otorhinolaryngology, plastic & reconstructive surgery, podiatry, and urology.

Dental Procedures:

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 Procedures:

Frenum Release/Frenectomy; Drainage (abscess); Flap Surgery; Biopsy (incisional & excisional); Aphthous Ulcers (incision & excision); Incision of Infection when used with Antibiotic Surgery; Excision & Ablation of lesions, benign & malignant oral cavity tumors, and hemangiomas; Salivary Gland Pathologies; Preprosthetic Gum Preparation, Leukoplakia; Partial Glossectomy; Peridontial Gum Resection; Homeostasis; Operculectomy; Crown Lengthening (soft tissue).

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7. Technological Characteristics Comparison to Predicate Devices

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

Predicate 510(k)	**LS-1005 K123037 K132661**	**AE-LS Acc. K081612 / K121471**	**Luxar LX-20 SP K960475**	**Lutronic DENTA II K091320**	**Lumenis AcuPulse™ K100415**
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	N/A	RF	DC	DC
Output Power (W)	2-10	N/A	2-20	0.5 – 25	1 - 30
Pulsed Power (W)	2-10	N/A	2-20	.1 - 7	1 - 25
Gated PW (ms)	5-500	N/A	5-500	.004 - 5	50 - 1000
Gated Rep. Rate (pps)	1 or 2-20	N/A	2-20	1 – 180 / 1 - 700	1 - 100
Superpulse (W)	2-5	N/A	2-10	.1 - 7	.5 - 10
Superpulse Peak (W)	30	N/A	50	N/A	N/A
Beam Delivery System	Flexible Fiber Waveguide	Flexible Fiber Waveguide	Flexible Fiber Waveguide	Articulated Arm	Articulated Arm
System HxWxD (in)	40x15x15	N/A	36x14x14	39x14x18	47x15x16
System Weight (lb)	47	N/A	42	77	108
Mobility	4 Wheels & Handle	N/A	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.	115 VAC	N/A	115 VAC	110/220 VAC	100-240 VAC

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8. Performance Testing

The LightScalpel LS-10 CO_2 Laser System has been evaluated for performance equivalent to predicate devices through a combination of (1) verification and validation tests per product requirements and specifications and (2) inspections and tests derived from applicable regulations and safety standards as noted below.

21 CFR 1040, Performance Standards for Light-emitting Products

IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-2-22, Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60825-1, Safety of laser products – Part 1: Equipment classification, requirements and user's guide

9. Animal and Clinical Testing

Device performance evaluation did not involve Animal of Clinical Testing.

10. Conclusions

A comparison between the LS-1005 and the predicated carbon dioxide lasers shows that these devices have similar laser characteristics and output parameters and therefore a determination of equivalence can be made between the predicate devices and the LS-1005.

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

January 2, 2014

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

Re: K132661
Trade/Device Name: LightScalpel LS-1005
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: December 3, 2013
Received: December 5, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Binita S. Ashar -S
2014.01.02 18:45:06 -05'00'

Binita S. Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132661

Device Name: LightScalpel® LS-1005 CO_2 Laser System

Indications for Use:
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Dental Procedures:
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).

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Frenum Release/Frenectomy; Drainage (abscess); Flap Surgery; Biopsy (incisional & excisional); Aphthous Ulcers (incision & excision); Incision of Infection when used with antibiotic therapy; Excision & Ablation of lesions, benign & malignant lesions, oral cavity tumors, and hemangiomas; Salivary Gland Pathologies; Preprosthetic Gum Preparation, Leukoplakia; Partial Glossectomy; Periodontial Gum Resection; Homeostasis; Operculectomy; Crown Lengthening (soft tissue).

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

For NRO
Atiq Chowdhury -S

(Division Sign-Off) for BSA
Division of Surgical Devices
510(k) Number K132661