

K030147

Attachment 7
510(k) Summary Statement for the Modified
Lumenis Family of UltraPulse SurgiTouch CO₂ Laser Systems

I. General Information

APR 15 2003

Submitter: Lumenis, Inc.
2400 Condensa Street
Santa Clara, CA 95051

Contact Person: Anne C Worden
Regulatory Consultant

Summary Preparation Date: January 12, 2003

II. Names

Device Names: Modified Lumenis Family of UltraPulse SurgiTouch
CO₂ Laser Systems

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Lumenis Family of UltraPulse Encore CO₂ Laser Systems (K022060);
- Lumenis Family of UltraPulse CO₂ Laser Systems (K963339).

IV. Product Description

The modified Lumenis family of UltraPulse SurgiTouch CO₂ Laser Systems are comprised of the following main components:

- A laser console
- A laser console tower
- A counterbalanced articulated arm and delivery system
- Control and display panel
- System microprocessor control electronics
- A covered footswitch or handswitch for specific delivery device accessories
- An optional air purge pump system with an insufflator filter for purge of delivery device accessories
- Operating software
- A variety of delivery device accessories or handpieces, including a pattern generator

V. Indications for Use

Lumenis UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers (and their delivery accessories) are used to deliver light energy and are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

In addition, the Lumenis UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers are safe and effective when indicated for use in specific surgical applications 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.

VI. Rationale for Substantial Equivalence

The modified Lumenis family of UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers (and their delivery accessories) share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the predicate devices, including the Lumenis UltraPulse Encore CO₂ Surgical Laser Systems (K022060) and the Lumenis (formerly Coherent Medical Group) UltraPulse CO₂ Surgical Laser Systems (K963339). In addition, medical and clinical data demonstrated that UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers are safe and effective when indicated for use of additional specific applications in a variety of medical specialties.

VII. Safety and Effectiveness Information

Medical and clinical study information was provided to demonstrate that the modified Lumenis family of UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers are safe and effective, when indicated in specific applications in the medical specialties of 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.

VIII. Conclusion

The modified Lumenis family of UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers (and their delivery accessories) were found to be substantially equivalent to the predicate Lumenis family of UltraPulse Encore Carbon Dioxide Surgical Lasers (K022060), and to the Lumenis family of UltraPulse Carbon Dioxide Surgical Lasers (K963339). The modified Lumenis family of UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers share the same intended uses, similar indications for use, and identical technological characteristics, and thus are substantially equivalent to, the currently marketed predicate devices.

Medical and clinical study information was provided to demonstrate that the modified Lumenis family of UltraPulse SurgiTouch Carbon Dioxide Surgical Lasers are safe and effective, when indicated in specific applications in the medical specialties of 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2003

Ms. Anne C. Worden
Regulatory Consultant
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K030147

Trade/Device Name: 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: II

Product Code: GEX

Dated: January 13, 2003

Received: January 15, 2003

Dear Ms. Worden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

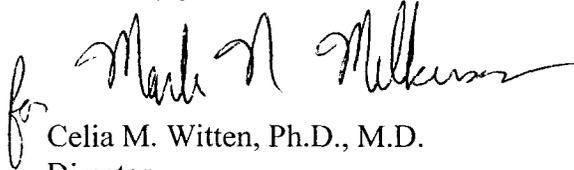
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 - Ms. Anne C. Worden

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the right of the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030147

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K030147

Device Name: Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers

Indications For Use:

The Modified Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers (and the delivery accessories that are used with them to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The Modified Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers are indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery as follows:

Dermatology & Plastic Surgery

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

- laser skin resurfacing;
- laser derm-abrasion;
- laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for treatment of:

- wrinkles, rhytids, and furrows (including fine lines and texture irregularities).

Clinical study demonstrated that skin resurfacing of wrinkles, rhytids, and furrows with the UltraPulse CO₂ laser increases the amount of sub-epidermal collagen.

*** Page 1 of 8 (Indications For Use Continued on Next Page; 8 pages total) ***

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K030147
OR Over-The-Counter Use _____

Prescription Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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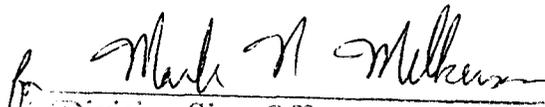
Indications For Use:

Continued from previous page:

Dermatology & Plastic Surgery, continued

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;
- vermilionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- cheilitis, including actinic cheilitis;
- lentiginos, 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


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Device Name: Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers

Indications For Use:

Continued from previous page:

Dermatology & Plastic Surgery, continued

Laser ablation, vaporization and/or excision for complete and partial nail matrixectomy

Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- lipectomy;
- verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts;

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

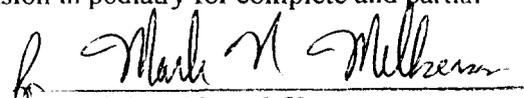
Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

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

- verrucae vulgares/plantar (warts), including paronychial, periungal, and subungual warts;
- fungal nail treatment;
- porokeratoma ablation;
- ingrown nail treatment;
- neuromas/fibromas, including Morton's neuroma;
- debridement of ulcers;
- other soft tissue lesions.

Laser ablation, vaporization and/or excision in podiatry for complete and partial matrixectomy;


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Indications For Use:

Continued from previous page:

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for treatment of:

- choanal atresia;
- leukoplakia, including oral, larynx, uvula, palatal, 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, neoplasma) and tonsil ablation/tonsillotomy;
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- benign and malignant lesions and fibromas (nose and nasal passages);
- benign and malignant tumors and fibromas (oral);
- stapedotomy/stapedectomy;
- acoustic neuroma in the ear;
- superficial lesions of the ear, including chondrodermatitis nondularis chronica helices/Winkler's disease;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy (tympanic membrane fenestration);
- uvulopalatoplasty (LAUP, laser UPPP);
- turbinectomy and turbinate reduction/ablation);
- septal spur ablation/reduction and septoplasty;
- partial glossectomy;
- tumor resection on oral, subfacial and neck tissues;

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Mark A. McBean
 Division Sign-Off
 Division of General, Restorative
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Indications For Use:

Continued from previous page:

Otolaryngology (ENT) - continued

- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivectomy

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology (GYN) for treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), 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 GYN laparoscopy, for treatment of:

- endometrial lesions, including ablation of endometriosis;
- excision/lysis of adhesions;
- salpingostomy;
- oophorectomy/ovariectomy;
- fimbrioplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;
- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy

for Mark A. Melburn

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Division of General, Restorative
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Indications For Use:

Continued from previous page:

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 (e.g. 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

Orthopedics

Incision/excision and vaporization of soft tissue in orthopedic surgery. Applications include:

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

Mark J. Miller
for

Division Sign-Off
Division of General, Restorative
and Neurological Devices

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Device Name: Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers

Indications For Use:

Continued from previous page:

General/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/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;

for Mark A. Milburn
 (Division Sign-Off)
 Division of General, Restorative
 and Neurological Devices
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Indications For Use Statement as Requested by FDA

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Device Name: Lumenis Family of UltraPulse SurgiTouch CO₂ Surgical Lasers

Indications For Use:

Continued from previous page:

Dental/Oral Surgery - continued

- 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

for Mark A. Miller

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Division of General Restorative
and Neurological Devices

Device ID: K030147

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