OCT 3 0 2002

K022060

Attachment 15
510(k) Summary Statement for the
Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers and Delivery Device Accessories

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Contact Person:	Lisa G. McGrath Sr. Regulatory Affairs Associate
Summary Preparation Date:	June 21, 2002

II. Names

Device Names:	Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

The Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers are substantially equivalent to the predicate devices, including the Lumenis, Inc. (formerly Coherent Medical Group) UltraPulse S Series Carbon Dioxide Surgical Lasers (K974789), the Lumenis, Ltd. (formerly Sharplan Lasers, Inc.) Model 700 and 1000 Series CO_2 Surgical Lasers (K935563), the Lumenis Ltd. (formerly Sharplan Lasers, Inc.) Model 20c, 30c and 40c CO_2 Surgical Lasers (K963229); the Lumenis, Ltd. (formerly Sharplan Lasers, Inc.) Model 1080 CO_2 Surgical Laser System (K933918); the Lumenis, Ltd. (formerly ESC Medical Systems) Luxar modified LX-20 CO_2 Surgical Laser System (K991628); the Aesculap-Meditec MultiPulse CO_2 Laser (K983215); and the MedArt® Corp. Uni-Laser 450-P CO_2 Laser System (K991297).

The modified Delivery Device Accessories for use with the Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers are substantially equivalent to delivery devices previously cleared as being compatible with Sharplan Laser Systems and include the following: focused spot handpieces with reusable and single use tip accessories (K933918); Fiber/Waveguide handpieces (K900076 and K950725); Scanner devices (K955621, K960521 and K963339); and scanner handpieces (K951204 and K963229); bronchoscopes and accessories (K822136 and K943700) and micromanipulators (K933918, K881953 and K951204). The Lumenis Stand-Alone Air Purge Pump and Related Accessories compatible for use with the Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers is substantially equivalent to the Lumenis gas purge accessories previously cleared in K951812.

Attachment 15
510(k) Summary Statement for the
Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers and Delivery Device Accessories, Con't.

IV. Product Description

The Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers and Delivery Device Accessories are intended to be used to deliver carbon dioxide light energy for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in a variety of medical specialties.

Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers 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 Encore 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 Encore 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2002

Lumenis, Inc.
Anne Worden
Regulatory Affairs
2400 Condensa Street
Santa Clara, California 95051-0901

Re: K022060
Trade/Device Name: Lumenis Ultrapulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories
Regulation Number: 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: September 27, 2002
Received: September 30, 2002

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.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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" (21 CFR Part 807.97). 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,

Miriam C Provost

for 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

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse® Encore™ Carbon Dioxide Surgical Laser and Delivery Devices**

Indications For Use:

The Lumenis UltraPulse Encore Carbon Dioxide 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 Lumenis UltraPulse Encore Carbon Dioxide 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 &/or vaporization) for treatment of:
- wrinkles, rhytids, and furrows

*** 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)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

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, &/or treatment of:

- keratoses, including actinic keratosis;
- solar/actinic elastosis;
- cheilitis, including actinic cheilitis;
- lentigines;
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids;
- hemangiomas (including Buccal and port wine);
- tattoos;
  telangiectasia;
- removal of small skin tumors;
- superficial pigmented lesions;
- adenosebaceous hypertrophy;
- rhinophyma reduction;
- cutaneous papilloma (skin tags);
- milia;
- debridement of eczematous or infected skin;
- basal and squamous cell carcinoma;
- nevi, including spider and epidermal;
- neurofibromas;
- tricoepitheliomas;
- xanthelasma palpebrarum;
- syringoma

*** Indications For Use Continued on Next Page (2 of 8) ***

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

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;

Laser incision &/or excision of soft tissue for the performance of blepharoplasty.

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

Podiatry

Laser ablation, vaporization &/or excision of soft tissue for the reduction, removal, &/or treatment of:
- verrucae vulgares/plantar (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;

*** Indications For Use Continued on Next Page (3 of 8) ***

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

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 nodules and polyps;
- 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;
- stenosis, including subglottic stenosis;
- tonsillectomy (including tonsilar cryptolysis and neoplasma);
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules and tumors (larynx, pharynx, trachea);
- benign and malignant lesions (nose and nasal passages);
- benign and malignant tumors (oral);
- stapedotomy/stapedectomy;
- acoustic neuroma in ear;
- superficial lesions of the ear;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy;

*** Indications For Use Continued on Next Page (4 of 8) ***

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

Indications For Use:

Continued from previous page:

Otolaryngology (ENT), con't.

- uvulopalatoplasty (LAUP, laser UPPP);
- turbinectomy;
- partial glossectomy;
- tumor resection on oral, subfacial and neck tissues;
- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivectomy

Gynecology

Laser incision, ablation and/or vaporization of soft tissue in 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 and perineal;
- leukoplakia (vulvar dystrophies);
- incision and drainage of Bartholin's and nabothian 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;

*** Indications For Use Continued on Next Page (5 of 8) ***

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

Indications For Use:

Continued from previous page:

GYN Laparoscopy, con't.

- fimbroplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;
- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy

Neurosurgery

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

Cranial

- posterior fossa tumors;
- peripheral neurectomy;
- benign and malignant tumors and cysts (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;

*** Indications For Use Continued on Next Page (6 of 8) ***

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

Indications For Use:

Continued from previous page:

Orthopedics, con't.

General
- debridement of traumatic wounds;
- debridement of decubitus and diabetic ulcers;
- microsurgery;
- artificial joint revision;
- PMMA removal;

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;
- 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;

*** Indications For Use Continued on Next Page (7 of 8) ***

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022060

Device Name: **Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Devices**

Indications For Use:

Continued from previous page:

Dental/Oral Surgery, con't.

- frenectomy (frenum release);
- excision and ablation of benign and malignant lesions;
- homeostasis;
- operculectomy;
- crown lengthening;
- removal of soft tissue, cysts and tumors;
- oral cavity tumors and hemangiomas;
- abscesses;
- extraction site hemostasis;
- salivary gland pathologies;
- preprosthetic gum preparation;
- leukoplakia;
- partial glossectomy;
- periodontal gum resection

Genitourinary

Incision/excision and vaporization of soft tissue in genitourinary procedures. Applications include:

- benign and malignant lesions of external genitalia;
- condyloma;
- phimosis;
- erythroplasia

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022060