JUL 23 2008

Section 5 – 510(k) Summary or 510(k) Statement

K080463

I. General Information

Submitter: Alma Lasers, Ltd.
14 Halamish Street (PO Box 3021)
Industrial Park,
Caesarea, 38900 ISRAEL

Contact Person: Tatiana Epstein
Regulatory Affairs Manager

Summary Preparation Date: June 2, 2008

II. Names

Device Names: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Primary Classification Names: Laser Instrument, Surgical Powered

III. Predicate Devices

- Lasering SLIM Evolution Family of CO_2 Lasers and Delivery Device Accessories (K063001)
- PhotoMedex LaserPro CO_2 Carbon Dioxide Laser System (K040234)
- Modified Lumenis Family of UltraPulse SurgiTouch CO_2 Laser Systems (K030147)
- Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories (K022060)

IV. Product Description

The Alma Lasers ThermoXEL™ CO_2 Laser System and delivery device accessories consist of the following major components:

1. Laser system console (containing the optical bench assembly and laser, the microcontroller control electronics and system software, the high voltage power supply, the laser cooling system, the compressed air-purge system, and the service panel)
   a. LCD control panel
   b. Keypad
2. 7-joint articulated arm
3. Footswitch
4. Variety of Delivery Device Handpieces (single spot, scanner, pixel)

V. Indications for Use

The Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in the medical specialties as defined in Section 4 of the present submission.

VI. Rationale for Substantial Equivalence

The Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories share the same or similar indications for use, operation, overall technical and functional capabilities, and therefore are substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories are substantially equivalent to the predicate devices.

VIII. Conclusion

The Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories were found to be substantially equivalent to the predicate devices.

The Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alma Lasers, Ltd.
% A. Worden Consulting
Ms. Anne Worden
Regulatory Consultant
3637 Bernal Avenue
Pleasanton, California 94566

JUL 23 2008

Re: K080463
Trade/Device Name: Alma Lasers ThermoXEL™ CO2 Laser System and Delivery Device Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical insgrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 2, 2008
Received: June 5, 2008

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K08**

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use:

The Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee).

The Alma Lasers ThermoXEL™ CO_2 Laser System is cleared for use for the particular indications 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 the treatment of:

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

Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO_2 laser increases the amount of sub-epidermal collagen.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080963

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the 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;
- vermillionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- chelitis, including actinic chelitis;
- lentigines, including lentigo maligna or Hutchinson's malignant freckle;
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids including acne keloidalis nuchae;
- hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telagiectaticum);
- tattoos;
- 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;

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K103046

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

Dermatology & Plastic Surgery, continued

- nevi, including spider, epidermal and protruding;
- neurofibromas;
- laser de-epithelialization;
- tricoepitheliomas;
- xanthelasma palpebrarum;
- syringoma

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

Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungaual 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.

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

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510(k) Number K103463

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

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 or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the 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;

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of General, Restorative, and Neurological Devices

510(k) Number K08 0443

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

Otolaryngology (ENT), continued

- laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue;
- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodivertuculostomy (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, trachcobronchial/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;
- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivoctomy.

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

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Division of General, Restorative, and Neurological Devices

510(k) Number K100406

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

Gynecology (GYN)

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

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminate, 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;
- fimbroplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;

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

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510(k) Number K080460

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

GYN Laparoscopy, continued

- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy.

Neurosurgery

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

Cranial

- posterior fossa tumors;
- peripheral neurectomy;
- benign and malignant tumors and cysts (e.g. gliomas, menigiomas (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.

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

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510(k) Number K080463

Indications for Use Statement

510(k) Number (if known): **K08**

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

Orthopedics

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

Arthroscopy

- menisectomy;
- chodromalacia;
- chondroplasty;
- ligament release (lateral and other);
- excision of plica;
- partial synovectomy.

General

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

General/Thoracic Surgery

Incision, excision and vaporization and 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;

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

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510(k) Number K080403

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

General/Thoracic Surgery, continued

- 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;

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

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Division of General, Restorative, and Neurological Devices

510(k) Number K080463

Indications for Use Statement

510(k) Number (if known): K08

Device Name: Alma Lasers ThermoXEL™ CO_2 Laser System and Delivery Device Accessories

Indications for Use - Continued from the previous page:

Dental/Oral Surgery, continued

- 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 and of soft tissue in genitourinary procedures. Applications include:

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

The Alma Lasers ThermoXEL™ CO_2 Laser System Pixel Handpieces are indicated for use in soft tissue for:

Dermatology & Plastic Surgery

- Skin resurfacing

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

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510(k) Number K100463