K072182

JUN 27 2008

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

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 12, 2008

II. Names

Device Names: Alma Lasers Family of Thermo-XEL Handpieces

Primary Classification Names: Accessory for, Laser Powered Surgical Instruments

III. Predicate Devices

- Lasering SLIM Evolution Family of CO_2 Lasers and Accessories (K063001)
- Lumenis ActiveFx with UltraPulse Encore (K022060)
- Lumenis UltraPulse with Scanner (K963339 and K951812)
- Reliant Technologies Fraxel SR1500 Laser Systems and Accessories (K070284)
- MSq Family of Lovely Light/Laser Systems (K042000)
- Alma Lasers Harmony XL Multi-Application Platform and Thermoelectric Cooler (K072564)

IV. Product Description

The Alma Lasers Family of Thermo-XEL Handpieces is comprised of the following main components:

- Thermo-XEL Handpiece body
- Adapter attachments:
  - CO_2 laser adapter attachment, as required, to attach the handpiece body to the qualified CO_2 or Er:YAG laser system
  - Er:YAG laser adapter attachment, as required, to attach the handpiece body to the qualified Er:YAG laser system

The Alma Lasers Family of Thermo-XEL Handpieces are provided as a non-sterile, cleanable, multiple use laser energy delivery device (accessory). The proximal end of the handpiece is designed to be attached, using the laser adapter, to the distal end of the articulated arm of compatible CO_2 (10.6 μm) or Er:YAG (2940 nm) laser systems as qualified by Alma Lasers for use with the Thermo-XEL Handpiece.

V. Indications for Use

The Alma Lasers Family of Thermo-XEL Handpieces is intended for use in surgical applications requiring the ablation, vaporization, and coagulation of soft tissue for compatible CO_2 and 2940 nm Er:YAG laser systems cleared for use in the medical specialty of Dermatology and Plastic Surgery to which they are attached.

The Alma Lasers Family of Thermo-XEL Handpieces is indicated for use in soft tissue for:

DERMATOLOGY AND PLASTIC SURGERY:

- Skin resurfacing

VI. Rationale for Substantial Equivalence

The Alma Lasers Family of Thermo-XEL Handpieces shares the same or similar indications for use, operation, overall technical and functional capabilities, and therefore is 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 Family of Thermo-XEL Handpieces is substantially equivalent to the predicate devices.

VIII. Conclusion

The Alma Lasers Family of Thermo-XEL Handpieces was found to be substantially equivalent to the predicate devices.

The Alma Lasers Family of Thermo-XEL Handpieces 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

JUN 27 2008

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

Re: K072182
Trade/Device Name: Alma Lasers Family of Thermo-XEL Handpieces
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: June 12, 2008
Received: June 13, 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
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): K072182

Device Name: Alma Lasers Family of Thermo-XEL Handpieces

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

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

510(k) Number K072182