Appendix 7 – 510(k) Summary for the Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL]

I. General Information

Submitter: Alma Lasers, Ltd.
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ISRAEL

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Regulatory Affairs Manager,
Alma Lasers, Ltd.

Anne Worden
Regulatory Consultant to Alma Lasers, Ltd.

Summary Preparation Date: September 19, 2007

II. Names

Device Names: Alma Lasers Family of Accent™ RF Systems

Primary Classification Names: Electrosurgical cutting and coagulation device and accessories

III. Predicate Devices

- Alma Lasers, Ltd. - Accent™ (K070004)

IV. Product Description

The Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL] is comprised of the following main components:

- Console
  - Bipolar RF handpieces (normal and small-tip)
  - Unipolar RF handpieces (normal and unilarge)
- Control panel
- Footswitch.

V. Indications for Use

The Alma Lasers Family of Accent™ RF Systems is intended for use in dermatologic and general surgical procedures.

The Indications for Use of the Accent™ RF Systems are provided in Appendix 4.

VI. Rationale for Substantial Equivalence

The Alma Lasers Accent XL™ RF device shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate Accent™ system.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers Accent XL™ RF device is substantially equivalent to the predicate Accent™ system.

VIII. Conclusion

The Accent XL™ RF device was found to be substantially equivalent to the predicate Accent™ system.

The Alma Lasers Family of Accent™ RF Devices shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alma Lasers, Ltd.
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OCT 5 2007

Re: K072699
Trade/Device Name: Alma Lasers Family of Accent™ RF Systems
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 19, 2007
Received: September 24, 2007

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 Office of Compliance at (240) 276-0115. 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 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

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 (DGRND/GSDB)
D.O.
f/t:GJM:kxl:10-01-07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

510(k) Number (if known): K072699

Device Name: **The Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL]**

Indications for Use:

The Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL] is intended for use in dermatologic and general surgical procedures.

The Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL] is indicated for the non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar handpieces.

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)

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

510(k) Number K072699