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

I. General Information

JAN 12 2009

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

Contact Person: Tatiana Epstein
Regulatory Affairs Manager
+972-4-627-5357

Summary Preparation Date: January 8, 2009

II. Names

Device Name(s): Accent UniForm Massager Handpiece/Module

Primary Classification Name(s): Massager, vacuum, light induced heating

III. Predicate Devices

- Cutera Multimodal Cellulite Device (CMMCD) (K080300);
- Biocellulase, Inc. (aka SmoothShapes & Eleme Medical) SmoothShapes (K053611);
- Syneron Medical VelaSmooth Shaper (K050397);
- Alma Lasers Family of Accent RF Systems [Accent, Accent XL] (K072699, K070004).

IV. Product Description

The Accent UniForm Massager handpiece/module is a cleanable, reusable radiofrequency (RF) energy delivery and skin mechanical manipulation/massage device (accessory) intended for use with the Alma Lasers Family of Accent RF Systems.

The Accent UniForm Massager handpiece/module is comprised of the following main components:

- Handpiece Tip with Massage Ring
- Handpiece Body
  - Handle – used for holding the handpiece
  - RF emission indicator – blue LED illuminates prior to- and during the RF energy emission
  - Thermo-electric cooler – integrated within the handpiece, provides contact cooling
  - Umbilical cable – contains hot and cold water tubes (cooling system), RF-power cable and the communication cable that controls the operation of the handpiece
  - Handpiece connector – connects the handpiece to its port. It incorporates an integrated impedance matching network (IMN) and a memory chip (i-button) that stores information about the handpiece and the parameter settings. It also houses the water tube quick-connectors.

V. Intended Use & Indications for Use

Intended Use

The Accent UniForm Massager handpiece/module is intended to be used with the Alma Lasers Family of Accent™ RF Systems for use in dermatologic and general surgical procedures.

Indications for Use

The massage component of the Alma Lasers Accent UniForm Massager Handpiece/Module is intended for use with the Alma Lasers Family of Accent RF Systems to provide:

- Temporary reduction in the appearance of cellulite.

Simultaneous application of RF energy and mechanical manipulation of the skin by the Alma Lasers Accent UniForm Massager Handpiece/Module is intended for use with the Alma Lasers Family of Accent RF Systems to provide:

- Temporary reduction in the appearance of cellulite.

VI. Rationale for Substantial Equivalence

The Accent UniForm Massager handpiece/module shares the same or similar indications for use, device 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 Accent UniForm Massager handpiece/module is substantially equivalent to the predicate devices.

VIII. Conclusion

The Accent UniForm Massager handpiece/module was found to be substantially equivalent to the predicate devices.

The Accent UniForm Massager handpiece/module 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

JAN 12 2009

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

Re: K082622
Trade/Device Name: Accent UniForm Massager Handpiece/Module
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: NUV, GEI, ISA
Dated: December 16, 2008
Received: December 22, 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): K082622

Device Name: Accent UniForm Massager Handpiece/Module

Indications for Use:

Intended 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)

Michael D. Jackson for MAM

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

510(k) Number K082622