K090571

Section 5– 510(k) Summary

AUG 13 2009

I. General Information

Submitter: Alma Lasers, Ltd.
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Summary Preparation Date: July 13, 2009

II. Names

Device Names: Alma Lasers ALEX755 Module

Primary Classification Names: Laser Instrument, Surgical, Powered

III. Predicate Devices

- K070805 - Ultrawave II EX 1320 - Quanta System SpA
- K042474 - ARION - WaveLight Laser Technologie, AG
- K034030 - Cynosure Apogee Elite Laser - Cynosure, Inc.
- K031488 - Cynosure Apogee-TKS II Laser - Cynosure, Inc.
- K992757 - Cynosure Apogee Laser - Cynosure, Inc.
- K040055 – Polylase LP - DDC Technologies, Inc.
- K010715 - AL40 - DDC Technologies, Inc.
- K032991 - Light Age EpiCare Aexandrite Laser - Light Age, Inc.
- K973354 - Sharplan EpiTouch Model 5000 Alexandrite Laser System - Sharplan Lasers, Inc.
- K971874 - Sharplan EpiTouch Model 5000 Alexandrite Laser System - Sharplan Lasers, Inc.

IV. Product Description

The Alma Lasers ALEX755 Module is an additional module to the existing Alma Lasers, Ltd. Harmony XL™ Multi-Application Platform (previously cleared under K072564).

The pistol-shaped Alex755 laser module incorporates a solid state Alexandrite rod laser medium and a xenon flash lamp as the heart of the optical bench. The flash lamp pumped Alexandrite rod emits light through an aperture located on the module tip. The laser beam is delivered when the operator presses both the footswitch, and the handpiece trigger.

The Alma Lasers ALEX755 Module is comprised of the following components:

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- An 'umbilical' cable and connector, that is permanently attached to the ALEX755 module body and semi-permanently attached to the laser system
- Electrical cables (to provide power to the light source and to connect to a memory device that identifies the module)
- A supply and return water line (to remove the heat generated)
- Module body (shells) housing the module internals and connecting to the umbilical.

The operator holds the handpiece by its handle in order to position the module tip against the patient's skin. Optional air-cooling can be provided.

V. Indications for Use

The Alma Lasers ALEX755 Module is indicated for permanent hair reduction, and the treatment of vascular lesions and benign pigmented lesions.

VI. Rationale for Substantial Equivalence

The Alma Lasers ALEX755 Module shares the same indications for use, the operation, 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 ALEX755 Module is substantially equivalent to the predicate devices.

VIII. Conclusion

The Alma Lasers ALEX755 Module was found to be substantially equivalent to the predicate devices.

The Alma Lasers ALEX755 Module shares the same or similar indications for use, similar design and functional features with, and thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Alma Lasers, Ltd.
% Alma Lasers, Inc.
Ms. Anne Worden
Regulatory Consultant
485 Half Day Road, Suite 100
Buffalo Grove, Illinois 60089

AUG 13 2009

Re: K090571
Trade/Device Name: Alma Lasers ALEX755 Module
Regulation Number: 21 CFR 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: July 13, 2009
Received: July 15, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~K08~~ K090571

Device Name: **Alma Lasers ALEX755 Module**

Indications for Use:

The Alma Lasers ALEX755 Module to be used with the Harmony XL™ Multi-Application Platform is indicated for permanent hair reduction. Also indicated for the treatment of vascular lesions and benign pigmented lesions.

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)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090571