OCT 2 4 2005

K 051214

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the Aluma™ Skin Renewal System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:	Lumenis, Inc.
Address:	2400 Condensa Street Santa Clara, CA 95051
Contact Person:	Connie Hoy
Telephone: Fax:	(408) 764-3303 (408) 764-3500
Preparation Date:	May 1, 2005
Device Trade Name:	Aluma™ Skin Renewal System
Common Name:	Electrosurgical cutting and coagulation and device and accessories
Classification Name:	Device, electrosurgical, cutting and coagulation device and accessories (see CFR 878.4400).
Legally Marketed Predicate Devices:	Thermage, Inc ThermaCool™ TC System (K033942 and K040135) Syneron Medical Ltd., Polaris™ (K031671)

System Description:	The Aluma Skin Renewal System is a non-invasive, non-ablative unit consisting of a user interface, a programmable logic controller (PLC), an RF power module, internal electronics, a vacuum pump, and a treatment handpiece with interchangeable tips (small and large). The interface allows the selection of treatment parameters by pressing on the treatment buttons; an LCD screen displays the current treatment settings. The PLC is a specially configured computer that provides the operational and safety function of the system. The RF power module provides RF energy to the handpiece, producing a sinusoidal signal at a 468 kHz frequency
Intended Use of the Device:	The Aluma Skin Renewal System is a non-invasive device intended for use in Dermatologic and General Surgical procedures non-invasive treatment of wrinkles and rhytids.
Technical characteristics;	The technological characteristics of the Aluma Skin Renewal System are the same or very similar to those of the claimed predicate devices.
Summary:	Based on the foregoing, the Aluma Skin Renewal System is substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2005

Connie Hoy
Global Director, RA/QS
Lumenis, Incorporate
2400 Condensa Street
Santa Clara, California 95051

Re: K051214
Trade/Device Name: Aluma Skin Renewal System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 22, 2005
Received: August 23, 2005

Dear Ms. Hoy:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Barbara Bue MD for

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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K051214

Device Name: Aluma Skin Renewal System

Indications for Use:

The Aluma Skin Renewal System is intended for use in Dermatologic and General Surgical procedures for the non-invasive treatment of wrinkles and rhytids.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (per 21 CFR 801.109) Over-the-Counter Use ___

Barbara Ann MD

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

510(k) Number K051214