DEC 17 2004

K043319

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness for the Clareon™ and Solarus™ pulsed light devices by Primary Technology is submitted in accordance with the requirements of 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:	Novalis Medical, LLC
Address:	1719 W. Kennedy Blvd Tampa, FL 33606
Contact Person:	Anthony M. Davis
Email:	adavis@primary-technology.com
Telephone:	TEL: 813-849-6362 FAX: 813-849-6364
Preparation Date:	September 19th , 2004
Device Trade Name:	1. Clareon™ Pulsed Light System 2. Solarus™ Pulsed Light System
Common Name:	1. Clareon™ 2. Solarus™
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (See: 21 CFR 878.4810) Panel: 79 Product Code: GEX
Legally marketed predicate Device(s):	**Palomar Medical Technologies, Inc.** EsteLux ™ (K020453), LuxV™ Handpiece (K040081) and LuxG™ Handpiece (K020941) **Lumenis (formerly ESC)** EpiLight™ (K963249) and Lumenis Family of IPL Systems{Specifically the Quantum SR model} (K020839) **Radiancy** Radiancy Acne System with ClearTouch LUA (K032205)
	System Description: The Clareon™ and Solarus™ Pulsed Light Systems are light-based medical device(s) which incorporate the use of the following accessory

	handpieces that are designed for specific treatments / uses: **HR Handpiece** - Permanent Hair reduction on all skin types; **SR Handpiece** - Photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels(facial and leg veins), and treatment of benign pigmented lesions and removal of unwanted hair; **VR Handpiece** - Photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels(facial and leg veins), and treatment of benign pigmented lesions; **AR Handpiece** - Treatment of inflammatory Acne on skin types I-IV.
Intended use:	The Clareon™ and Solarus™ Pulsed Light Systems are light-based medical device(s) designed for Permanent Hair reduction , Photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels(facial and leg veins), and treatment of benign pigmented lesions on all skin types. Treatment of inflammatory Acne on skin types I-IV.
Performance Data:	The differences in specifications of the Clareon™ and Solarus™ and the predicate device(s) do not result in different performances or raise new questions of safety or efficacy.
Conclusion:	Based on the foregoing, the Clareon™ and Solarus™ Pulsed Light Systems with accessory handpieces are substantially equivalent to the legally-marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Novalis Medical, LLC
C/o Mr. Daniel W. Lehtonen
Responsible Third Pary Official
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K043319
Trade/Device Name: Clareon™ Pulsed Light System and Accessories, Solarus™ Pulsed Light System and Accessories
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: November 20, 2004
Received: December 2, 2004

Dear Mr. Lehtonen:

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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Clareon™ Pulsed Light System**
Solarus™ Pulsed Light System

Indications for Use:

The Clareon™ and Solarus™ Pulsed Light Systems are light-based medical device(s) intended for use with the following:

HR Handpiece - Permanent hair reduction.
AR Handpiece – Treatment of inflammatory acne.
VR Handpiece - Photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels(facial and leg veins), and treatment of benign pigmented lesions.
SR Handpiece - Photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels(facial and leg veins), and treatment of benign pigmented lesions. Removal of unwanted hair.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K043319