JUN 2 0 2006

K061117

510(k) Summary of Safety and Effectiveness

Applicant: Nanolite Technology, Inc.

Address: 21250 Hawthorne Blvd., Suite 500
Torrance, California 90503

Phone: 909-598-5778

Fax: 909-598-7369

Contact Person: Hueng Khon Kim

Summary Preparation Date: May 17, 2006

Device Trade Name: Nanolite Skin Care System

Device usual name: Low level light therapy device

Device Classification:

Regulatory Class: Class II

Product Code: GEX

Classification Panels: General and Plastic Surgery

Regulation Number: 21 C.F.R. 878.4810 (Laser surgical instrument for use in general and plastic surgery and in dermatology)

Note: The Nanolite Skin Care System is not a laser product; however, the applicant believes that this classification is the most applicable.

Description of the Device:

The Nanolite Skin Care System is a light-based device that uses LED to stimulate and regenerate skin cells. The device delivers red light at 640 nm.

The principal parts of the device are: the base that contains the power supply; a LED module containing surface mount device chip LEDs; one arm attached to the LED module to be positioned for patient treatment; and a control unit consisting of an LCD panel with a touch-screen display.

The software in the LCD panel is preprogrammed to provide for twenty minutes of exposure time to LED lights per treatment. During each treatment, the lights are turned on and off to prevent desensitization of the skin area that is being treated and to increase the stimulative effects of the energy from the LED.

The Nanolite Skin Care System generates output power equal to 170 mW/cm^2 from each LED. Since Nanolite has 6 LEDs per square centimeter, it generates total power dissipation per square meter of 1020 mW/cm^2. The device software is programmed to control the output power to create a standard dose of approximately $90J/cm^2$ for each treatment.

Predicate Devices:

The Nanolite Skin Care System is substantially equivalent to Omnilux Revive manufactured by Photo Therapeutics Limited (K030426).

Indications:

The Nanolite Skin Care System is indicated to treat pigmented lesions.

Substantial Equivalence:

The Nanolite Skin Care System and the predicate device are all light devices that use light emitting diodes to treat dermatological conditions by exposing the surface of the skin to light at precise wavelengths. They have the same intended use and general indications for use, are similarly designed, and have similar principles of operation, performance and technological characteristics. Although there are some differences in the technological characteristics of the Nanolite Skin Care System and its predicate devices, those differences do not raise new questions of safety or efficacy. Therefore, the Nanolite Skin Care System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2006

Nanolite Technology, Inc.
c/o Daniel W. Lehtonen
Intertek Testing Services
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K061117
Trade/Device Name: Nanolite Skin Care System™
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: June 2, 2006
Received: June 5, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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: K061117

Device Name: Nanolite Skin Care System™

Indications for Use:

The Nanolite Skin Care System is indicated to treat pigmented lesions.

Prescription Use X OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(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 K061117