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510(k) Summary

Submitted by:	LED Technologies, LLC 133 County Road 17 Elizabeth, CO 80107 USA
Contact Person:	Lewis Ward L.W. Ward and Associates, Inc. 4655 Kirkwood Court Boulder, CO 80301 USA 303-530-3279 lwward@qwest.net
Date Prepared:	5-13-2010
Device Trade Name:	dpl® Nüve
Common Name:	LED lamp
Regulation Number:	878.4810
Classification Name:	Infrared lamp OHS: light-based over-the-counter wrinkle reduction GEX: powered laser surgical instrument (for acne treatment)
Intended Use:	Intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. Indicated as an over-the-counter phototherapy device for the treatment of mild to moderate acne.
Technological Characteristics:	The dpl® Nüve is a lightweight, handheld, light emitting diode (LED) device with interchangeable heads which emit light energy. A blue LED head in the 415 nm spectrum is used in treatment for mild to moderate inflammatory acne. A red head at 625 nm and a purple head (infrared) in the 830 nm spectrum are used in combination for reduction of periorbital wrinkles. The handle of the device contains the electronics of the device including a fan for cooling and an automatic shut-off safety feature
Substantial Equivalence:	The device is substantially equivalent in function and technology To the Omnilux New U for periorbital wrinkle treatment and the Tanda Skin Care product for treatment of acne. Conclusions drawn from the nonclinical and clinical tests demonstrate that the

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device is as safe and effective as the legally marketed predicate devices.

Test Data:

The dpl® Nüve has been demonstrated safe by testing and meeting IEC 60601-1, EN 60601-1-2, and EN 60601-2-22. Patient contact materials are demonstrated safe under ISO 10993 testing. The dpl® Nüve does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LED Technologies, LLC
% L. W. Ward and Associates, Inc.
Mr. Lewis Ward
4655 Kirkwood Court
Boulder, Colorado 80107

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Re: K101382
Trade/Device Name: dpl® Nuve
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: OHS, GEX
Dated: November 01, 2010
Received: November 03, 2010

Dear Mr. Ward:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number (if known): K101382

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Device Name: dpl® Nuve

Indications for Use:

Intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Indicated as an over-the-counter phototherapy device for the treatment of mild to moderate acne.

Prescription Use _____ AND/OR Over-the-Counter Use __X__
(Part 21 CFR 801 Subpart D) (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)

Mark RP Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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