NUVO INC.

JAN 2 8 2009

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510 (k) SUMMARY

Submitter: Nuvo Inc
5368 Kuhl Road
Erie, PA 16407

Contact Person: Curt Vander Schaaff

Trade Name: Verde LED Surgical Lighting System

Common Name: Light Surgical, Ceiling Mounted

Classification Number: 21 CFR 878.4580

Product Code: FSY

Predicate Devices:

- Aurora LED Series Surgical Light (Skytron)
  510 (k): K071698 dated July 6, 2007
  Product Code: FSY

- Harmony LED-1 Surgical Lighting System (Steris)
  510 (k): K072072 dated October 5, 2007
  Product Code FSY

- iLED Surgical Lighting System (Trumpf Kreuzer Medizin)
  510 (k): K061317 dated June 22, 2006
  Product Code FSY

Device Description:

The proposed Verde LED Surgical Light System is the next generation variable pattern / intensity surgical light designed to provide visible illumination of the surgical field and the patient during surgical and non-surgical procedures.

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Intended Use:

The proposed Verde LED Surgical Light System is a variable pattern / intensity surgical light designed to provide visible illumination of the surgical field and the patient during surgical and non - surgical procedures.

Description of Safety:

The performance of the Verde LED Surgical Lighting System meets the general requirements for safety as defined in CEI/IEC 60601-1 and IEC 60601-2-41 for Medical Electrical Equipment.

Substantial Equivalence:

The proposed Verde LED Surgical Light System is a variable pattern / intensity surgical light designed to provide visible illumination of the surgical field and the patient during surgical procedures. The Proposed Device is identical in function, intended use, components, technology and performance to the predicate devices: Aurora LED Series Surgical Light (Skytron) (K071698), Harmony LED-1 Surgical Lighting System (Steris) (K072072), and iLED Surgical Lighting System (Trumpf Kreuzer Medizin) (K061317).

The differences between the proposed and predicate devices are limited to differences in design, material, and operational. These differences do not raise any new issues of safety and efficiency

Performance Testing:

Performance testing was conducted to verify that the Verde LED Surgical Lighting System meets the requirements for Medical Electrical Equipment as defined in CEI / IEC 60601-1 and IEC 60601-2-41.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NUVO, Inc.
% Mr. Curt Vander Schaaff
QA/RA Manager
5368 Kuhl Road
Erie, Pennsylvania 16407

JAN 2 8 2009

Re: K083323
Trade/Device Name: The Verde LED Surgical Light System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: October 20, 2008
Received: December 2, 2008

Dear Mr. Schaaff:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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

510(k) Number: Unknown K083323

Device Name:

Indications for Use:

The Verde LED Surgical Light System, subjected in this submission is a variable pattern / intensity surgical light designed to provide illumination of the surgical field and patient during surgical and non-surgical procedures.

Prescription Use (Per 21 CFR 801.109 X) OR Over- the- Counter Use_____

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 K083323