K071698

SKYTRON®
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Grand Rapids, MI 49512
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JUL - 6 2007

510 (k) SUMMARY

SUBMITTER: SKYTRON
5085 CORPORATE EXCHANGE BLVD.
GRAND RAPIDS, MI 49512

CONTACT PERSON(s) MR. LARRY PEREZ, MS. MARY MURPHY

PREPARATION DATE: MAY 3RD, 2007

COMMON NAME: AURORA LED SERIES

CLASSIFICATION NAME: LIGHT, SURGICAL, CEILING MOUNTED

DEVICE DESCRIPTION: The Aurora LED series surgical light is suitable for all types of surgical procedures. The Aurora series surgical light is intended to provide local surgical site illumination throughout the patient's body providing a high-intensity, shadow-free "cold" pattern of light. The lights consist of several modules containing LEDs (light emitting diodes) and optical color corrective reflectors. Each light head features independent focus capability allowing the user to adjust the illumination parameters. The light intensity is adjustable between 10% - 100% and a color temperature of 4000K - 4500K creating the infinite capability to adapt to different situations. LEDs offer low heat radiation and increased illumination and are energy saving.

INTENDED USE OF THE DEVICE: The Aurora LED series surgical light is intended to provide local illumination at the surgical site on the patient's body at Hospitals, Clinics, VA's, Freestanding Surgical centers, Ambulatory/Care Centers and Doctor's offices

PREDICATE DEVICE: TRADE NAME: STELLAR
510 (k): K002463
PRODUCT CODE: FSY

INDICATIONS FOR USE

The SKYTRON Aurora series surgical light fixture is intended to be used by medical personnel for the purpose of illuminating surgical sites

SUBSTANTIAL EQUIVALENCE:

THE AURORA LED SERIES IS SUBSTANTIALLY EQUIVALENT TO THE SURGICAL LIGHT ***STELLAR SERIES. (K002463)*** ANY EXISTING DIFFERENCES BETWEEN THE ***STELLAR SERIES*** AND THE AURORA LED SERIES HAS NO NEGATIVE EFFECT OF THE EFFECTIVENESS OR SAFETY. THE AURORA LED SERIES ACTUALLY AUGMENTS THE USEFULNESS AND RELIABILITY IN THE CHOSEN APPLICATIONS.

PRIMARY DIFFERENCE;

THE LIGHT SOURCE IS A LIGHT EMITTING DIODE (LED) WHICH HAS AN EXPECTED LIFE TIME THAT IS 4 TIMES GREATER THAN TRADITIONAL INCANDESCEBT BULBS AND IS HIGHLY ENERGY EFFICIENT.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2007

Skytron, Inc.
% Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
2307 Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K071698
Trade/Device Name: Aurora LED Series Surgical Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: June 19, 2007
Received: June 21, 2007

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 (if known): K071698

Device Name: Aurora LED Series Surgical Light

Indications For Use:

The SKYTRON Aurora Series surgical light fixture is intended to be used by medical personnel for the purpose of illuminating surgical sites.

Prescription Use___X__ (Part 21 CFR 801 Subpart D) AND/OR OVER THE COUNTER USE_____ (21 CFR 801 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

DIVISION SIGN-OFF

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

510(k) Number K071698