K100702

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Appendix 4F

510(K) Summary

StarTrol™ LED Surgical Light System

JUL 20 2010

Submitted by:
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Date prepared: March 9, 2010

Proprietary Name: StarTrol™ LED Lighting System

Common Name: Minor Surgical Light

Device Classification: Surgical Light (78 FSY)
Class II, as listed per 21 CFR 878.4580

Predicate Device:
Next Generation Surgery Light
Medical Illumination International
K003489
Product Class: FSS, FTD, FSY

AIM
Burton Medical Products Corporation
Pre-Amendment
Product Class: FSY

Description of Device:

The StarTrol LED Lighting System is a Class II medical device that provides an illumination field for general examination and minor surgery. The lighting system utilizes LED's for illumination and is powered from standard AC voltage sources. The head design is comprised of multiple LED's (Light Emitting Diodes). The LED head is mounted such that it can be moved and oriented by the operator to place the illumination field on the subject by means of a removable handle (sterile, single use handle covers are available). The light head is balanced with a counterweight to provide flexibility and exact placement without the drifting of the light head. Maneuverability of the light head requires minimal force by the clinician to quickly and easily place it in the desired position. The intensity of illumination is variable.

Intended Use:

The StarTrol LED Lighting system is designed to provide a visible illumination of the examination /surgical field of the patient during surgical and non-surgical procedures.

Non-Clinical Comparisons to Predicate Devices:

The StarTrol LED Lighting System and the predicate devices are alike in they have variable intensity surgical lights which provide illumination, are available in various mounting configurations, similar power sources, and intended uses. The differences between the StarTrol LED Lighting System and the predicate devices are in the general appearance of the light, and in the case of the Next Generation the light source used is a halogen bulb, where as the StarTrol and the AIM feature LED's as the light source.

Test Data:

The test data supports conformance to:

UL 60601-1 Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-2-41 Medical Electrical Equipment – Part 2-41: Particular Requirements for the Safety of Surgical Luminaires and Luminaires for
Diagnosis

IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility

IEC 60601-1-4 Medical Electrical Equipment – Part 1-4 General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems

IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – collateral Standard: Usability

CSA C22.2 No. 60601.1 Medical Electrical Equipment, Part 1: General Requirements for safety

CSA C.22.2 No. 60601-2-41 Medical Electrical Equipment – Part 2-41: Particular Requirements for the safety of surgical

Clinical Data:

No clinical date is required for this device classification submission. The StarTrol LED Lighting System is a light that is substantially equivalent to our predicate devices, which have been available for decades and doing a clinical evaluation would be of no benefit.

Conclusion:

The modifications between the StarTrol LED Lighting System and the predicate devices (Next Generation and the AIM) are limited to the differences in the design of the light, some materials, and the basic operations. These differences in the light do not create any new issues in the safety and efficacy. Based on the information provided in this 510(k) Premarket Notification, we conclude that the StarTrol LED Lighting System is substantially equivalent to the predicate devices and is safe and effective when used as intended.

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

JUL 20 2010

Huot Instruments, LLC
% Ms. Anne Ward
N50 W13740 Overview Drive
Suite A
Menomonee Falls, Wisconsin 53051

Re: K100702
Trade/Device Name: StarTrol™ LED Lighting System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY, FSS, FTD
Dated: July 14, 2010
Received: July 16, 2010

Dear Ms. 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

Appendix 1A

Indications for Use

510(k) Number: K100702

Device Name: StarTrol LED Lighting System

Indications for Use:

The StarTrol LED Lighting system is designed to provide a visible illumination of the examination /surgical field of the patient during surgical and non-surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100702