ECOLAB®

APR 0 8 2014

K133554

Section 5: 510(k) Summary

Surgical Light Handle Cover

As required by 21 CFR 807.92.

Date: November 11, 2013

Administrative Information

Submitter: Microtek Medical Inc., an Ecolab Company

Establishment Registration Number: 1043582

Contact Person: Andy Roller
370 Wabasha Street North
St. Paul, MN 55102-1390
Sr. Regulatory Specialist
651.293.2080

Device Identification

Device Name:	Surgical Light Handle Cover
Common Name:	Surgical Light Accessory
Device Classification Name:	Light, Surgical, Accessories
Device Classification:	Class II
Panel:	General and Plastic Surgery
Classification Regulation:	878.4580
Product Code:	FTA
Performance Standards:	No Recognized Consensus Standards

Predicate Device: Surgical Lamp Handle and Cover, cleared on 3/20/1999 via K901154

Trade Name: Skytron Disposable Light Handle Cover

Device Description

The Surgical Light Handle Cover is a polycarbonate injection molded device shaped to fit a surgical light that has release buttons protruding from the surgical light handle. The Surgical Light Handle Cover has apertures located at the end of the device, proximal to the surgical light, which correspond to the release buttons on the surgical light handle. When the Surgical Light Handle Cover is attached to the light, the release buttons will interface with the apertures to secure the Surgical Light Handle Cover to the light handle.

The Surgical Light Handle Cover is hollow in the center, with transparent polycarbonate located near the distal end. The transparent end permits the use of a recording device, which may be mounted onto the surgical light. The transparent end allows light to pass through for the purpose of recording images, it does not provide image enhancement or magnification.

Statement of Intended Use

The Surgical Light Handle Cover is intended to be used as a disposable barrier for a surgical lighting system and which allows the surgical team member to manually adjust the lighting system. This is a single-use device.

Substantial Equivalence Discussion

The predicate device and design basis for the Surgical Light Handle Cover is the Microtek Medical Surgical Lamp Handle and Cover (K901154, cleared 3/20/1990). The fundamental scientific technology of the device remains unchanged in that it is a disposable sterile light cover that allows the user to adjust position of the light during surgical procedures. The following table illustrates the similarities and differences in the product designs.

Table 1: Substantial Equivalence

Property or Characteristic	**Proposed Device - Surgical Light Handle Cover**	**Predicate Device - Surgical Lamp Handle and Cover (K901154)**
Intended Use/Indications for Use	A device intended to be used as a disposable barrier for a surgical lighting system and which allows a surgical team member to manually	A device intended to be used as a disposable barrier for a surgical lighting system and which allows a surgical team

	adjust the lighting system. This is a single-use device	member to manually adjust the lighting system. This is a single-use device
Conditions of Use	Single Use, Disposable	Single Use, Disposable
Materials	Polycarbonate Handle Cover	Polypropylene Handle Cover
Property or Characteristic	**Proposed Device - Surgical Light Handle Cover**	**Predicate Device - Surgical Lamp Handle and Cover (K901154)**
Color	Clear - Frosted	White
Sterility	Provided sterile	Provided sterile
Sterility Assurance Level	10^{-6} via EO Gas	10^{-3} via Gamma Radiation
Principle of Operation	Sterile cover to allow manipulation of a surgical light	Sterile cover to allow manipulation of a surgical light
Interface with Surgical Light	Fully detachable	Lamp Handle – Not detachable Handle Cover – Fully detachable
Transparent Distal End	Yes	No

Performance Data Summary

Table 2: Performance Data Summary of the Surgical Light Handle Cover

Requirement	**Specification**	**Method**	**Result**
Packaging	Simulated Distribution Test	ASTM D4169	Pass
	Dye Migration Test	ASTM F1929	Pass
	Seal Peel Test	ASTM F88	Pass
	Inspection for Shipping Damage	Visual Inspection	Pass
Sterility	SAL 10^{-6}	ISO 11135-1	Pass
	EO/ECH Residuals	ISO 10993-7	Pass
Material Compatibilty Evaluation	Cytotoxicity	ISO Elution	Pass
	Material Leachables	USP Physical-Chemical Analysis	Pass
Functional Requirements	Product must be easily installed and removed	Attached/Detached Surgical Light Handle Cover to surgical light	Pass
	Product must not interfere with the functionality of surgical light	With Surgical Light Handle Cover attached: rotate light, move light in transverse direction, compare visual clarity	Pass

Substantial Equivalence Conclusion

The differences between the Surgical Light Handle Cover and the predicate device do not constitute a new intended use, and the differences in technological characteristics do not raise different questions of safety and effectiveness. Furthermore, the changes to the device design do not impact the fundamental scientific technology or principle of operation, which is to allow a user to manipulate a surgical light during surgical procedures using a disposable sterile cover.

The Surgical Light Handle Cover is substantially equivalent to the predicate device cleared under K901154.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 8, 2014

Microtek Medical, Incorporated
An Ecolab Company
Mr. Andy Roller
Senior Regulatory Specialist
370 Wabasha Street North
St. Paul, MN 55102

Re: K133554
Trade/Device Name: Surgical Light Handle Cover
Regulation Number: 21 CFR 878.4580
Regulation Name: Light, Surgical, Accessories
Regulatory Class: II
Product Code: FTA
Dated: January 30, 2014
Received: February 12, 2014

Dear Mr. Roller:

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Statement of Indications for Use

510(k) Number (if known): K133554

Device Name: Surgical Light Handle Cover

Model Number: B1-715-65

Indications For Use: A device intended to be used as a disposable barrier for a surgical lighting system and which allows a surgical team member to manually adjust the lighting system. This is a single-use device

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 CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S
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