K 113330

JAN 12 2012

510(k) Summary
SensorMed CableCap™
510(k) Number ~~K101496~~ K113330
Manufacturer Identification

Submitted by: SensorMed, Inc.
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Date Prepared: October 10, 2011

Device Identification
Proprietary Name CableCap™
Common Name Light Cable Burn and Fire Prevention Device
Classification Name Accessory to Fiberoptic Surgical Light
Device Classification 21 CFR 878.4580
Proposed Regulatory Class Class II
Device Product Code FST

Device Description
The CableCap device attaches to the distal end of high intensity light cables. The device absorbs and diffuses the light transmitted through the cable in order to prevent patient burns and igniting flammable items in the surgical suite.

There are three separate models made for the three types of light cables:

CableCap Model	Light Cable Type
WLF-D	Wolf
STZ-D	Storz
ACM-D	ACMI

Intended Use of the Device

The device absorbs and diffuses the light transmitted through the cable in order to prevent patient burns and igniting flammable items in the surgical suite.

Predicate Device
SensorMed Reusable CableCap device (K101496)

Technology Comparison

Both devices are constructed from biocompatible plastics. Both are accessories to high intensity light cables. Both devices attach to the distal end of light cables and modify the outgoing light stream to benefit minimally invasive surgical procedures. Please see the table below for a device comparison table.

	Reusable CableCap	**Disposable CableCap**
Attenuates light from a medical light box	X	X
Diffuses light in multiple directions	X	X
Is manufactured from a combination of biocompatible plastic	X	X
Is autoclave-able	X	no
Improves surgical procedure for patient	X	X
Does not directly treat or diagnose patient	X	X
Works with multiple light sources and different intensities	X	X

Performance Testing

Bench-top physical testing was performed by Materials, Engineering, and Testing Corp. located in Oak Ridge, TN. Their Accreditation number is 59214 and they are ISO/IEC 17025:2005 compliant. As an extreme scenario, we assumed that the device might remain in contact with a patient's skin for 30 minutes. As an extra precaution, we doubled this time to 60 minutes for test runs. As indicated in the report included in the testing section, the maximum temperature for the tip of the device was only 95 °F, which is still well below the standard.

Therefore, SensorMed is confident that the device temperature will not be a concern even if used for extended periods of time.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the CableCap. The results of these activities demonstrate that the CableCap is safe and effective when used in accordance with its intended use and labeling.

Therefore, CableCap is considered substantially equivalent to the predicate device.

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

SensorMed, Incorporated
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Vice President of Engineering
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JAN 12 2012

Re: K113330
Trade/Device Name: CableCap
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FST
Dated: November 9, 2011
Received: November 14, 2011

Dear Mr. Milam:

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.

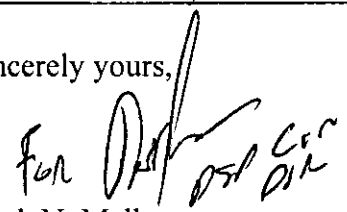
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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):___ Kxxxxxx K113330

Device Name:__CableCap

Indications For Use:

The device absorbs and diffuses the light transmitted through the cable in order to prevent patient burns and igniting flammable items in the surgical suite.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113330