NOV 25 2011

5. 510(K) SUMMARY

Schott North America
Light Guide Cable
(per 21CFR 807.92)

K111342
1/2

1. SUBMITTER/510(K) HOLDER

Schott North America
122 Charlton Street
Southbridge, MA 01550

Contact Person: Nilesh Samant
Telephone: 1-508-765-9744

Date Prepared: May 11, 2011

2. DEVICE NAME

Proprietary Name: Light Guide Cable
Common/Usual Name: Fiberoptic Cable
Classification Name: Surgical Lamp

3. PREDICATE DEVICE

Endoscopic Fiber Optic Cable marketed by Isolux America, K991208

4. DEVICE DESCRIPTION

The Light guide cable consists of glass fibers which are glued or fused into ferrules on both ends. The ends are polished to effectively transmit light and are equipped with standard endoscope connectors to transmit visible light from the light source to the intended instrument. The fibers are covered by Silicone sheathing for ease of handling and protecting the fibers from damage. The device is intended to be Ethylene Oxide (EtO) sterilized by the user. Sterilization information is contained in section 14.

5. INTENDED USE

The Light Guide Cable is indicated for use in transmitting light for illumination purposes from an illuminator to various instruments such as headlights, microscopes and endoscopes, providing illumination in body cavities during examinations or surgical procedures.

6. Technological Characteristics and Substantial Equivalence

The characteristics of the Light Guide Cable are substantially equivalent to the following current legally marketed predicate devices based on intended use, typical clinical use, and operational and fundamental technological characteristics.

Endoscopic Fiber Optic Cable marketed by Isolux America, K991208

A detailed side-by-side comparison of the Light Guide Cable with the identified predicate device is provided in the substantial equivalence discussion in this premarket notification.

7. Performance Testing

The Light Guide Cable performance testing includes electrical safety testing and sterilization validation to the appropriate FDA Recognized Consensus Standards. The results of this performance testing conclude that the technological characteristics have not diminished the safety and effectiveness of the Light Guide Cable when compared to the predicate device.

8. Conclusion

Based on the similarities in indication for use, design, functional, and operational features the Light Guide Cable has demonstrated substantial equivalence to the listed legally marketed predicate device and any differences do not affect the product's safety or effectiveness.

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

NOV 25 2011

Schott North America
% Medical Device Consultants, Inc.
Mr. Jeffrey Roberts
40 Plain Street
North Attleboro, Massachusetts 02760

Re: K111342
Trade/Device Name: Light Guide Cable
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: HBI
Dated: November 09, 2011
Received: November 10, 2011

Dear Mr. Roberts:

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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

K111342

510(k) Number (if known): Not yet assigned

Device Name: Light Guide Cable

Indications for Use:

The Schott Light Guide Cable is indicated for use in transmitting light for illumination purposes from an illuminator to various instruments such as headlights, microscopes and endoscopes, providing illumination in body cavities during examinations or 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 K111342