DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 9, 2015

Katalyst Surgical, LLC
Ms. Meryl Koch
Quality Assurance and Regulatory Affairs Manager
754 Goddard Avenue
Chesterfield, MO 63005

Re: K141781
Trade/Device Name: The Kogent™ Spetzler Lighted Suction Tubes
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: HBI, FST
Dated: February 23, 2015
Received: March 20, 2015

Dear Ms. Koch:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) Number (if known): K141781

Device Name: The Kogent™ Spetzler Lighted Suction Tubes

Indications for Use: The Kogent™ Spetzler Lighted Suction Tubes are intended to provide surgical site illumination from a high intensity light source.

Prescription Use ___√____ (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 (OD

K141781

5 510(k) Summary

Manufacturer: Katalyst Surgical, LLC
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636-787-0603 (fax)

Contact Person: Meryl Koch
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Date Prepared: **June 25th, 2014**

Device Trade Name: Kogent™ Spetzler Lighted Suction Tubes

Common Name: Lighted Suction Tubes

Device Classification: 21 CFR 878.4580: Surgical Lamp

Classification Name: General and Plastic Surgery

Class: II

Product Code: HBI, FST

Indications for Use:
The Kogent™ Spetzler Lighted Suction Tubes are intended to provide surgical site illumination from a high intensity light source.

Device Description:
This device is a disposable Kogent™ Spetzler Lighted Suction Tubes, designed for single use in surgical procedures. Lighted Suction Tubes require connection with a suitable operating room suction system to deliver suction as well as with a suitable illumination machine. Lighted Suction Tubes are designed to provide illumination while having the ability to aspirate the surgical site. The devices are provided sterile by Ethylene Oxide and in sterile packaging.

Predicate Device:
The Kogent™ Spetzler Lighted Suction Tube was shown to be substantially equivalent to the previously cleared devices: Invuity® Eigr™ Surgical Illumination System, K113697.

Substantial Equivalence:

SUMMARY OF EVALUATION

Bench testing demonstrates that Kogent™ Spetzler Lighted Suction Tubes are validated for their Indications for Use.

SUMMARY OF EQUIVALENCE

FDA File Reference No.	510(k) No. K113697
TECHNOLOGICAL CHARACTERISTICS	Comparison Result
Indications for Use	Equivalent
Target Population	Equivalent
Design	Similar
Materials	Equivalent
Performance	Equivalent
Sterility	Equivalent
Biocompatibility	Equivalent
Maximum Power Input	Equivalent
Energy Used and/or Delivered	Equivalent
Compatibility with Environment and Other Devices	Similar
Where Used	Equivalent
Illumination Pattern	Equivalent
Illumination Intensity	Similar
Max. Tip Temperature	Similar

Design: The tip configuration for the predicate device is either a Yankauer suction tip or a Frazier suction tip. The tip configuration of the subject device is a cone shaped tip. The difference in design between the cone shaped tip of the Kogent™ Spetzler Lighted Suction Tubes and the suction tips of the predicate device does not affect the safety or effectiveness of the Lighted Suction Tubes when used as indicated. The handle configuration for the predicate device is a vertical "pistol" grip designed to be held in one hand. The handle configuration of the subject device is a horizontal handle designed to be held in one hand between the thumb and fingers. The differences in design between the vertical "pistol" handle of the predicate device and the horizontal handle of the subject device does not affect the safety or effectiveness of the Lighted Suction Tubes when used as indicated.

Compatibility with Environment and Other Devices: The connector of the predicate device is an ACMI connector and the connector of the subject device is a Storz style connector. The difference in connector types does not affect the safety or effectiveness of the Lighted Suction Tubes when used as indicated.

Illumination Intensity: The illumination intensity of the Kogent Spetzler Lighted Suction Tubes is similar to the Invuity Eigr Surgical Illumination System. The intensity of the illumination is slightly higher for the subject device. This difference does not impact the safety or the effectiveness of the Kogent Lighted Suction Tube as the outcome is additional light to illuminate the surgical site.

Maximum Tip Temperature: The maximum tip temperature of the Kogent Spetzler Lighted Suction Tubes is similar to the Invuity Eigr Surgical Illumination System. The temperature is slightly lower for the subject device. This difference does not impact the safety or the effectiveness of the Kogent Lighted Suction Tube as the outcome is a cooler tip and less risk of overheating.

Non-Clinical Testing: The Kogent™ Spetzler Lighted Suction Tubes were tested in accordance with IEC 60601-1 and satisfy testing requirements. It is believed that the predicate device also claims compliance with IEC 60601-1. Bench testing was performed on the Kogent™ Spetzler Lighted Suction Tubes to verify the design inputs. The measured values and visual evidence confirmed that the Kogent™ Spetzler Lighted Suction Tubes conform to design dimensions and characteristics. Biocompatibility testing was performed on the materials present within the Kogent™ Spetzler Lighted Suction Tubes. All biocompatibility testing results satisfied the corresponding ISO 10993 specific requirements.

Conclusion

The Kogent™ Spetzler Lighted Suction Tubes were shown to be substantially equivalent to the previously cleared device with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.