510(k) Summary

Manufacturer: Katalyst Surgical, LLC
754 Goddard Avenue
Chesterfield, MO 63005
636-536-5950 (phone)
636-787-0603 (fax)

Contact: Mona Dean
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636-536-5950 (phone)
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Date Prepared: October 5, 2012

Device Trade Name: Kogent Bipolar Forceps

Common Name: Bipolar Forceps

Classification: 21 CFR 878.4400; Electrosurgical cutting and coagulation device and accessories

Class: II

Product Code: GE1

Indications for Use:
The Kogent Disposable Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation of tissue. The Kogent Disposable Irrigating Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation and irrigation of tissue.

Device Description:
This device is a disposable bipolar forceps, designed for single use in electrosurgical procedures. They require connection with a suitable bipolar cable to the bipolar output of an electrosurgical generator. These forceps are designed to grasp, manipulate, coagulate, and irrigate, when applicable, selected tissues. The irrigation tube is designed to carry fluid to the tips of the instrument. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator and activated by a footswitch. The devices are provided sterile by ethylene oxide and in sterile packs.
Predicate Device:
The Kogent Bipolar Forceps was shown to be substantially equivalent to the previously cleared devices: Synergetics Disposable Spetzler-Malis Bipolar forceps K121426 and Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps K110924.

Performance Testing Summary:
The Kogent Bipolar Forceps performance testing is summarized below.

<table>
<thead>
<tr>
<th>Test Criteria</th>
<th>Description</th>
<th>Lower Spec</th>
<th>Upper Spec</th>
<th>Units</th>
<th>Standard Reference</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF Leakage Current</td>
<td>Leakage current</td>
<td></td>
<td>Leakage = 1.8 x 10^-20 A</td>
<td>mA</td>
<td>201.8.8.3.102 IEC 60601-2-2 EdS 2009</td>
<td>PASS</td>
</tr>
<tr>
<td>HF Dielectric Strength</td>
<td>Active accessory HF dielectric strength</td>
<td></td>
<td>120% of the rated accessory voltage</td>
<td>KV</td>
<td>201.8.8.3.103 IEC 60601-2-2 EdS 2009</td>
<td>PASS</td>
</tr>
<tr>
<td>Mains Frequency</td>
<td>The test duration shall be 30 seconds for active connectors</td>
<td>Pass/ Fail - 3.0KV at 60HZ Frequency</td>
<td>KV</td>
<td>201.8.8.3.104 IEC 60601-2-2 EdS 2009</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>Dielectric Withstand</td>
<td>Scan the cord of active accessory for 5 minutes.</td>
<td>Pass/ Fail - 3.0KV at 60HZ Frequency</td>
<td>KV</td>
<td>201.8.8.3.104 IEC 60601-2-2 EdS 2009</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>Anchorage</td>
<td>Workmanship</td>
<td></td>
<td></td>
<td></td>
<td>201.8.10.4.2 IEC 60601-2-2 EdS 2009</td>
<td>PASS</td>
</tr>
<tr>
<td>Resistance/Continuity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.2 Ohms</td>
<td></td>
</tr>
</tbody>
</table>
Substantial Equivalence:
Bench testing demonstrates that the Kogent Bipolar Forceps are substantially equivalent to the Synergetics Disposable Spetzler-Malis Bipolar forceps K121426 and Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps K110924.

SUMMARY OF EQUIVALENCE

<table>
<thead>
<tr>
<th>FDA File Reference No.</th>
<th>510(k) No. 510924</th>
<th>Comparison Result</th>
<th>510(k) No. 121426</th>
<th>Comparison Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TECHNOLOGICAL CHARACTERISTICS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Identical</td>
<td>Identical</td>
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<tr>
<td>Target Population</td>
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<td></td>
<td></td>
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<tr>
<td>Design</td>
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<tr>
<td>Materials</td>
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<tr>
<td>Performance</td>
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<tr>
<td>Sterility</td>
<td>Identical</td>
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<tr>
<td>Biocompatibility</td>
<td>Identical</td>
<td>Identical</td>
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<tr>
<td>Anatomical Sites</td>
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<tr>
<td>Human Factors</td>
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<tr>
<td>Energy Used and/or Delivered</td>
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<td></td>
<td></td>
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<tr>
<td>Compatibility with Environment and Other Devices</td>
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<td>Similar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where Used</td>
<td>Identical</td>
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<tr>
<td>Electrical Safety</td>
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<tr>
<td>Thermal Safety</td>
<td>Identical</td>
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<tr>
<td>Radiation Safety</td>
<td>Identical</td>
<td>Identical</td>
<td></td>
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</tr>
</tbody>
</table>

Conclusion
The Kogent Bipolar Forceps were shown to be substantially equivalent to previously cleared devices with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.
Katalyst Surgical, LLC
% Ms. Mona Dean
Quality and Regulatory Manager
754 Goddard Avenue
Chesterfield, Missouri 63005

Re: K123172
Trade/Device Name: Kogent Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 05, 2012
Received: December 06, 2012

Dear Ms. Dean:

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” (21 CFR 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,

Peter D. Rumm -S

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

Enclosure
Indications for Use

510(k) Number (if known): Pre-enact

Device Name: Kogent Bipolar Forceps

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Prescription Use ☑ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (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)

Dwight Yen
2012.12.20 12:33:10 -05'00'
(Division Sign-off)
Division of Surgical Devices
510(k) Number _K123172_________