October 7, 2022

Katalyst Surgical, LLC
Liz Morgan
Quality and Regulatory Specialist
754 Goddard Ave
Chesterfield, Missouri 63005

Re: K213610
Trade/Device Name: Kogent Disposable Copper Forceps, Kogent Disposable Irrigating Copper Forceps, Kogent Disposable Illuminating Copper Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 6, 2022
Received: September 6, 2022

Dear Liz Morgan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213610

Device Name
Kogent Disposable Copper Bipolar Forceps
Kogent Disposable Irrigating Copper Bipolar Forceps
Kogent Disposable Illuminating Copper Bipolar Forceps

Indications for Use *(Describe)*

The Kogent Disposable Copper Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation of tissue. The Kogent Disposable Copper Irrigating Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation and irrigation of tissue. The Kogent Disposable Copper Illuminating Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation and to supply light for surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

Contact: Liz Morgan
Katalyst Surgical, LLC
636-536-5950 (phone)
636-787-0603(fax)
e.morgan@katalystsurgical.com

Date Prepared: November 4, 2021

510(k) Number: K213610

Device Trade Name: Kogent Disposable Copper Bipolar Forceps
Kogent Disposable Irrigating Copper Bipolar Forceps
Kogent Disposable Illuminating Copper Bipolar Forceps

Common Name: Bipolar Forceps

Classification: 21 CFR 878.4400

Classification Name: Electrosurgical cutting and coagulation device and accessories

Class: II

Product Code: GEI

Indications for Use:

The Kogent Disposable Copper Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation of tissue. The Kogent Disposable Copper Irrigating Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation and irrigation of tissue. The Kogent Disposable Copper Illuminating Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation and to supply light for surgical procedures.

Device Description:
These devices are disposable bipolar forceps, designed for single use in general surgical 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, irrigate and illuminate, when applicable, selected tissues. The irrigation tube is designed to carry sterile fluid to the tips of the instrument. The illumination style forceps contain illumination fibers on each tine to deliver light to the surgical site. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator and activated by a footswitch. The forceps are provided sterile by ethylene oxide and in sterile pouches.

Predicate Device:
The Kogent Disposable Copper Bipolar Forceps was shown to be substantially equivalent to the previously cleared devices: Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps K110924, Synergetics Spetzler Malis Dual Illuminating Bipolar Forceps K160103, and Kogent Bipolar Forceps K123172.

Comparison of Technical Characteristics:

	Subject Device	**Predicate Device**
Device Name	**Kogent Disposable Copper Bipolar Forceps**	**Kogent Bipolar Forceps**
Company	Katalyst Surgical, LLC	Katalyst Surgical, LLC
K Number	K213610	K123172
Classification	Class II	Class II
Product Code	GEI	GEI
Indications for Use	Single use product sold sterile and are intended for use in electrosurgery for coagulation of tissue	Single use product sold sterile and are intended for use in electrosurgery for coagulation of tissue
Forceps Design	Bayonet Style	Bayonet Style
Patient Contact Material	Silver Plated copper base with PVDF insulation	Silver Plated aluminum base with PVDF insulation
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-6 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2
Size Offerings Overall Length	6.25, 7, 8, and 9 inches	7, 8, and 9 inches
Size Offerings Distal Tip	0.5mm, 1.0mm, 1.5mm	0.5mm, 1.0mm, 1.5mm
Packaging Configuration	Double Tyvek/Poly pouches	Double Tyvek/Poly pouches
Biocompatibility	Biocompatible per test reports	Biocompatible per test reports
Method of Sterilization	ETO	ETO
Sterility Assurance Level	10^{-6}	10^{-6}

	Subject Device	Predicate Device
Device Name	**Kogent Disposable Copper Irrigating Bipolar Forceps**	**Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps**
Company	Katalyst Surgical, LLC	Synergetics, Inc
K Number	K213610	K110924
Classification	Class II	Class II
Product Code	GEI	GEI
Indications for Use	Single use product sold sterile and are intended for use in electrosurgery for coagulation and irrigation of tissue	Sterile single use, for use in electrosurgery for coagulation and irrigation of tissue
Forceps Design	Bayonet Style	Bayonet Style
Patient Contact Material	Silver Plated copper base with PVDF insulation	Silver Plated aluminum base with PVDF insulation
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-6 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2
Size Offerings Overall Length	7,8 and 9 inch handles	7,8 and 9 inch handles
Size Offerings Distal Tip	0.5mm, 1.0mm, 1.5mm	0.5mm, 1.0mm, 1.5mm
Packaging Configuration	Double Tyvek/Poly pouches	Rigid PETG Tray with Tyvek 1073B Lid
Biocompatibility	Biocompatible per test reports	Biocompatible per test reports
Method of Sterilization	ETO	ETO
Sterility Assurance Level	10^{-6}	10^{-6}

	Subject Device	Predicate Device
Device Name	**Kogent Disposable Copper Illuminating Bipolar Forceps**	**Synergetics Spetzler Malis Dual Illuminating Bipolar Forceps**
Company	Katalyst Surgical, LLC	Synergetics, Inc
K Number	K213610	K160103
Classification	Class II	Class II
Product Code	GEI	GEI
Indications for Use	Single use product sold sterile and are intended for use in electrosurgery for coagulation and to provide light for surgical procedures	Single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue and to

		supply light for surgical procedures
Forceps Design	Bayonet Style	Bayonet Style
Patient Contact Material	Silver Plated copper base with PVDF insulation	Silver Plated aluminum base with PVDF insulation
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-6 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2
Size Offerings Overall Length	7,8 and 9 inch handles	8 and 9 inch handles
Size Offerings Distal Tip	0.5mm, 1.0mm, 1.5mm	0.5mm, 1.0mm, 1.5mm
Packaging Configuration	Double Tyvek/Poly pouches	Rigid PETG Tray with Tyvek 1073B Lid
Biocompatibility	Biocompatible per test reports	Biocompatible per test reports
Method of Sterilization	ETO	ETO
Sterility Assurance Level	10^{-6}	10^{-6}

Performance Data:
Clinical Testing was not required to prove substantial equivalence. Bench testing performed between the candidate device and the predicate devices indicates that the Kogent Copper Bipolar Forceps are substantially equivalent to predicate devices.

The product required the following other tests which were completed successfully:

Medical Electrical Equipment:
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
IEC 60601-2-2: 2017 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR 2:2007, AMD1:2012 or IEC 60601-1:2012
IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012

Biocompatibility:
ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

Sterilization:
ISO 11135:2014 Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices

Shelf Life:

ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Bench Testing
Thermal Conductivity
Non-Stick Ability
Average Flow Rate
Average Illumination Output
Average Temperature Rise due to Illumination Output
Thermal Effects on Tissue

Conclusion
The Kogent Disposable Copper 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.