June 19, 2020

Katalyst Surgical, LLC
Meryl K. Wilhelm
Director of Quality Assurance and Regulatory Affairs
754 Goddard Avenue
Chesterfield, Missouri 63005

Re: K192963
Trade/Device Name: Kogent TorUS Ultrasonic Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 17, 2019
Received: October 23, 2019

Dear Meryl K. Wilhelm:

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 and Part 809); 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192963

Device Name
Kogent TorUS® Ultrasonic Aspirator System

Indications for Use *(Describe)*
The Kogent TorUS® Ultrasonic Aspirator system is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue and hard tissue (e.g. bone) is desired, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: Meryl Koch Wilhelm
Katalyst Surgical, LLC
636-536-5950 (phone)
636-787-0603(fax)
m.koch@katalystsurgical.com

Date Prepared: June 18th, 2020

510(k) Number: K192963

Device Trade Name: Kogent TorUS® Ultrasonic Aspirator System

Common Name: Ultrasonic Surgical Aspirator

Classification Name: Aspirator, Surgical Ultrasonic

Device Class: Unclassified

Product Code: LFL;

Indications for Use:

The Kogent TorUS® Ultrasonic Aspirator system is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue and hard tissue (e.g. bone) is desired, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery.

Contraindications for Use:

The Kogent TorUS® Ultrasonic Aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Device Description:

The Kogent TorUS® consists of a console that provides power and control of the ultrasonic aspiration and irrigation functions, three surgical handpieces that provide the ultrasonic mechanical energy to the surgical site, a foot pedal to allow the user control over the ultrasonics, titanium tips (variety of models), irrigation sleeves, suction/irrigation system (manifold tubing and a vacuum canister) and accessories used for assembly/disassembly and reprocessing. The Kogent TorUS accommodates most commercially available suction canisters and optional specimen traps.

Predicate Devices:

510(k)	Company Name	Device Name
K190070	Stryker Instruments	Sonopet iQ Ultrasonic Surgical Aspirator
K010309	MUTOH America Co.	Sonopet Model UST-2001 Ultrasonic Surgical Aspirator

Comparison of Technical Characteristics:

	Subject Device	Predicate Device	Reference Device
Device Name	Kogent TorUS® Ultrasonic Aspirator System	Sonopet iQ Ultrasonic Aspirator System	Sonopet Model UST-2001 Ultrasonic Surgical Aspirator
Company	Katalyst Surgical, LLC	Stryker Instruments	Mutoh America Co.
K Number	Subject Device	K190070	K010309
Classification	Unclassified	Unclassified	Unclassified
Product Code	LFL	LFL	LFL
Indications for use	The Kogent TorUS® Ultrasonic Aspirator system is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue and hard tissue (e.g. bone) is desired, including Neurosurgery, Gastrointestinal and Affiliated Organ	The Stryker Sonopet iQ Ultrasonic Surgical System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft and hard tissue is desirable, including neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery,	The Stryker Sonopet Ultrasonic Surgical System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue is desirable, including neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery,

	Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery.	plastic and reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and thoracoscopic surgery.	plastic and reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and thoracoscopic surgery.
Contraindications	This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.	This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.	This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.
Design Specification	Mechanical Ultrasonic Energy Irrigation Aspiration	Mechanical Ultrasonic Energy Irrigation Aspiration	Mechanical Ultrasonic Energy Irrigation Aspiration
Energy source	AC powered from electrical mains through detachable cord	AC powered from electrical mains through detachable cord	AC powered from electrical mains through detachable cord
Electrical Classification	Class II	Class II	Class II
MR Safety	MR unsafe	MR unsafe	MR unsafe
System Activation Control Method	Foot pedal	Foot pedal	Foot pedal
Ultrasonic Energy Control	Piezo-electric, sinusoidal, non-continuous	Piezo-electric, sinusoidal, non-continuous	Piezo-electric, sinusoidal, non-continuous
Irrigation Control	Forced, via peristaltic pump	Forced, via peristaltic pump	Forced, via peristaltic pump
Aspiration	Vacuum Pump	Vacuum Pump	Vacuum Pump

Control			
Tip Lengths	10-20cm	11-20cm	9.7-20cm
Tip Application	Torque wrench	Torque wrench	Torque wrench
Functionalities	Fragmentation, emulsification, aspiration	Fragmentation, emulsification, aspiration	Fragmentation, emulsification, aspiration
Components	Console, handpiece, tubing, tips, irrigation sleeve, torque wrench, suction canister	Console, handpiece, tubing, tips, irrigation sleeve, torque wrench, suction canister	Console, handpiece, tubing, tips, irrigation sleeve, torque wrench, suction canister
Energy Mechanism	Ultrasonic Energy	Ultrasonic Energy	Ultrasonic Energy
Sterilization	Ethylene Oxide (disposable) and Steam (reusable)	Ethylene Oxide (disposable) and Steam (reusable)	Ethylene Oxide (disposable) and Steam (reusable)
Biocompatibility	Biocompatible per test reports	Biocompatible per test reports	Biocompatible per test reports
Handpiece Frequencies	25kHz	25kHz	25kHz and 34kHz
Aspiration Potential (vacuum pressure)	78kPa maximum	75.5kPa maximum	85kPa maximum
Volumetric Flow Rate	533mL/min (maximum)	Unknown	522mL/min (maximum)
Maximum Output Power	100W	Unknown	100W

The impact of the differences was evaluated through bench testing comparative studies as well as usability studies. These differences do not impact the intended use, indications for use, operating principle or energy source.

Performance Data:

Clinical Testing was not required to prove substantial equivalence. Bench testing performed between the candidate device and the predicate device indicates that the Kogent TorUS® Ultrasonic Aspirator System is substantially equivalent to the reference device. Testing included, but was not limited to:

Medical Electrical Equipment:

- IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability

Software:

- IEC 62304 Medical Device Software – Software Life Cycle Processes

Biocompatibility:

- ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity and Material-Mediated Pyrogenicity

Sterilization:

- ISO 11135 Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff

Shelf Life:

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

Bench Testing:

- Thermal Effects Testing at the Tip
- Suction and Aspiration Level Testing
- Surgical Bone Removal and Cutting Testing
- Soft and Fibrous Tissue Removal Testing

Conclusion

The Kogent TorUS® Ultrasonic Aspirator System was shown to be substantially equivalent to the previously cleared predicate device with respect to intended use and substantially equivalent to the reference device with respect to technological characteristics, performance characteristics, and biocompatibility.