February 3, 2022

Stryker Corporation
Thomas Flannelly
Staff Regulatory Affairs Engineer
4100 East Milham Ave.
Kalamazoo, Michigan 49001

Re: K213824
Trade/Device Name: Sonopet iQ Ultrasonic Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: January 14, 2022
Received: January 18, 2022

Dear Thomas Flannelly:

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,

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)*
K213824

Device Name
Sonopet iQ Ultrasonic Aspirator System

Indications for Use *(Describe)*
The Sonopet iQ Ultrasonic Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue and hard tissue is desirable, 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.

CONTRAINDICATION: This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Submitter Information

This Premarket Notification is submitted by:

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Contact Information

Thomas Flannelly
Staff Regulatory Affairs Engineer
Ph: 011-353-87-6487949
Email: Thomas.Flannelly@stryker.com
Date Prepared: 7 December 2021

Device Name

Subject Device Information

Subject Device Information		
Trade/ Proprietary Name		Sonopet iQ Ultrasonic Aspirator System
Primary	**Regulation Name**	Aspirator, Surgical Ultrasonic
	Review Panel	General and Plastic Surgery
	Product Code	LFL
	Regulatory Class	Unclassified

Predicate Device

The legally marketed predicate for the subject device is detailed in the table below.

Predicate Device Information

Predicate Device Trade Name	510(k)	Product Code	Manufacturer
Sonopet iQ Ultrasonic Aspirator System	K190070	LFL	Stryker Instruments

Indications for Use

The Sonopet iQ Ultrasonic Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue and hard tissue is desirable, 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.

CONTRAINDICATION: This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Device Description

The Sonopet iQ Ultrasonic Aspirator System is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective resection of target tissue while preserving vessels, ducts and other delicate structures. The system consists of a console which provides control and power functions, a surgical handpiece to provide ultrasonic energy (25kHz), sixteen (16) titanium tips with irrigation sleeves, and an Irrigation Suction Cassette.

The modification described here within is a software enhancement to the Console of the Sonopet iQ Ultrasonic Aspirator System, cleared under K190070. Specifically, the purpose of this software enhancement is to add an optional feature called Pulse Control.

Pulse Control provides an additional means of controlling the dose of ultrasonic energy by modulating the tip displacement amplitude and reduces tip temperature across the various aspirator tips while minimizing the associated reduction in hard tissue resection rate.

In conjunction with the addition of the Pulse Control feature, the memory control parameters on the Sonopet iQ Tips have been updated to enable amplitude modulated pulsing of the ultrasonic control output wave form.

Comparison of Technological Characteristics

A comparison of the technological characteristics of the subject device included in the scope of this Special 510(k) with the predicate is included in the table below.

Technological Comparison

DESCRIPTION	Subject Device	Predicate Device	Comparison Assessment
	Sonopet iQ Ultrasonic Aspirator System (Pulse Control)	**Sonopet iQ Ultrasonic Aspirator System (K190070)**	
Indications for Use	The Sonopet iQ Ultrasonic Aspirator is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue and hard tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated Organ surgery, urological, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, thoracic surgery, Laparoscopic surgery, and Thoracoscopic surgery.	The Sonopet iQ Ultrasonic Aspirator is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue and hard tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated Organ surgery, urological, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, thoracic surgery, Laparoscopic surgery, and Thoracoscopic surgery.	**Identical**
Classification of Device	Unclassified	Unclassified	**Identical**
Primary Product Code	LFL Surgical Ultrasonic Aspirator	LFL Surgical Ultrasonic Aspirator	**Identical**
Condition of Use	Reusable Single Use (In Case of the Tip and Sleeves)	Reusable Single Use (In Case of the Tip and Sleeves)	**Identical**
Type of Use	Prescription Use Only	Prescription Use Only	**Identical**
Patient Population	General	General	**Identical**
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.	**Identical**
Principle of Operation	The Sonopet iQ Ultrasonic Aspirator System has three major functional capabilities: ultrasonic energy, irrigation, and aspiration.	The Sonopet iQ Ultrasonic Aspirator System has three major functional capabilities: ultrasonic energy, irrigation, and aspiration.	**Identical**

DESCRIPTION	Subject Device	Predicate Device	Comparison Assessment
	Sonopet iQ Ultrasonic Aspirator System (Pulse Control)	**Sonopet iQ Ultrasonic Aspirator System (K190070)**	
Energy Source	AC Powered from Electrical Mains through detachable cord	AC Powered from Electrical Mains through detachable cord	**Identical**
Tissue Fragmentation Method	Ultrasonic Energy	Ultrasonic Energy	**Identical**
Ultrasonic Energy Method	Piezo-electric, sinusoidal, non-continuous and Pulse Control	Piezo-electric, sinusoidal, non-continuous	**Similar**
Irrigation Control	Forced, via peristaltic pump	Forced, via peristaltic pump	**Identical**
Aspiration Control	Vacuum	Vacuum	**Identical**
System Activation Control Method	Foot Pedal	Foot Pedal	**Identical**
Reprocessing Methods	Clean and Disinfect	Clean and Disinfect	**Identical**
Electrical Classification	Class II	Class II	**Identical**
MR Safety	MR Unsafe	MR Unsafe	**Identical**
Power Delivery Options	Constant, Variable, Pulsing (Pulse Control)	Constant, Variable	**Similar**
Aspiration Flow Technology	Vacuum pump, combination of pinch and solenoid valves	Vacuum pump, combination of pinch and solenoid valves	**Identical**

DESCRIPTION	Subject Device	Predicate Device	Comparison Assessment
	Sonopet iQ Ultrasonic Aspirator System (Pulse Control)	**Sonopet iQ Ultrasonic Aspirator System (K190070)**	
Aspiration Potential	75.5kPa Maximum	75.5kPa Maximum	**Identical**
Frequency	25kHz	25kHz	**Identical**
Primary User Interface	Power, Irrigation, Aspiration, and Pulse Control	Power, Irrigation, and Aspiration	**Similar**

Summary of Non-Clinical Testing

The intended use of the subject device and predicate are identical, and their technological characteristics are similar. The subject device is a modification of the predicate and utilizes the same design and operating principles. The device modifications do not raise any new or different questions of safety and effectiveness.

Risk management was conducted in accordance with ISO 14971.

The following testing was conducted to demonstrate that the modifications to the subject device are as safe and effective as the predicate.

- Software Verification Testing
- Validation Testing
- Performance Testing
- IEC 60601-1 Electrical Safety
- IEC 60601-1-2 EMC Testing

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the subject device are sufficient for their intended use, indications for use and support a determination of substantial equivalence.

Summary of Clinical Testing

Clinical testing was not required for this Special 510(k).

Conclusion

The proposed modifications to the subject device do not alter the indications for use, intended use, or its fundamental scientific technology. There are no differences in the indications for use and intended use between the subject and predicate devices.

The only technological difference is the addition of Pulse Control, which provides a means of controlling the dose of ultrasonic energy by modulating the tip displacement amplitude.

The modifications introduced raise no new or different issues of safety and effectiveness and testing has demonstrated substantial equivalence to the predicate device.