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510(k) Summary

807.92(a)(1) – Submitter Information	
510(k) Owner/Submitter:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700
Contact Person:	Julia L. Helgeson Principal RA Specialist
Registration Number:	1811755
Date Summary Prepared:	April 09, 2019

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807.92(a)(2) – Name of Device	
Trade Name(s):	Sonopet iQ Ultrasonic Aspirator System
Common Name:	Surgical Ultrasonic Aspirator
Classification Name:	Aspirator, Surgical Ultrasonic
Classification Panel:	General & Plastic Surgery
Device Class:	Unclassified
Product Code(s):	LFL

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807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed
Sonopet Model UST-2001 Ultrasonic Surgical Aspirator – K010309

807.92(a)(4) – 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 mechanical energy (25kHz), fifteen (15) titanium tips with irrigation sleeves, and an Irrigation Suction Cassette. Users may choose from three different styles of footswitches. An optional hand controller that allows adjustment of the console settings is also available. Control of the system functional outputs (ultrasonic energy, irrigation, and aspiration) is achieved via the console. The console interfaces with the irrigation suction cassette to control the levels of aspiration and irrigation at the surgical site. It also controls the energy delivered to the connected handpiece to control the motion of the tip. The settings on the console are adjusted directly on the console or via the optional connected hand controller. Activation of the system is controlled by pressing the treadle of a wired or wireless foot pedal. This system is for professional use only within a professional healthcare environment.

807.92(a)(5) – Intended Use of the Device	
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.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate
The subject and predicate devices are ultrasonic surgical instruments which use electrical energy in the ultrasonic frequency range to drive a tip for the fragmentation and emulsification of soft and hard tissue. The systems use irrigation at the surgical site to emulsify the fragmented tissue. The systems also use aspiration to remove the fragmented and emulsified tissue from the surgical site. The following primary characteristics are identical for the subject and predicate devices:

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Characteristic	Subject Device	Predicate Device
Energy Source	AC Powered from Electrical Mains through detachable cord	AC Powered from Electrical Mains through detachable cord
Operating Principle/ Functional Outputs	Mechanical Ultrasonic Energy Irrigation Aspiration	Mechanical Ultrasonic Energy Irrigation Aspiration
Tissue Fragmentation Method	Ultrasonic Energy	Ultrasonic Energy
Ultrasonic Energy Control	Piezo-electric, sinusoidal, non-continuous	Piezo-electric, sinusoidal, non-continuous
Irrigation Control	Forced, via peristaltic pump	Forced, via peristaltic pump
Aspiration Control	Vacuum	Vacuum
System Activation Control Method	Foot Pedal	Foot Pedal
Terminal Sterilization Methods	Ethylene oxide	Ethylene oxide
Reprocessing Methods (Sterile Reusable)	Manual or automated (mechanical) cleaning with Moist Heat Sterilization	Manual or automated (mechanical) cleaning with Moist Heat Sterilization
Reprocessing Methods (Non-sterile Reusable)	Clean and Disinfect	Clean and Disinfect
Electrical Classification	Class II	Class II
MR Safety	MR Unsafe	MR Unsafe

The following technological characteristics of the subject and predicate device systems differ. These differences and changes offer new or altered features over those of the predicate device, but do not impact the intended use, indications for use, operating principle, or energy source.

Characteristic	Subject Device	Predicate Device
Power Delivery Options	Constant, Variable	Constant
Aspiration Flow Control	Vacuum pump, combination of solenoid and pinch valves	Vacuum pump, combination of needle and pinch valves
Aspiration Potential (vacuum pressure)	75.5kPa maximum	85kPa maximum
Frequency	25kHz	25kHz and 34kHz
Accessory Connections/ Device Recognition	Keyed connectors, illuminated ports for status, RFID recognition, communication bus recognition	Keyed connectors, recognition by discrete component
Handpiece to Tip Assembly	In sterile field, direct torque with wrench (no need to rest in sterilization tray)	In sterile field, torque with wrench, requires sterilization tray to stabilize handpiece
Primary User Interface	Graphic User Interface (GUI), illuminated ports	Push button, LED indicators
Foot Pedal Options	Wired or wireless Basic or advanced features	Wired Basic
Tip Lengths	11 – 20cm	9.7 – 20cm

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Tip Distal Geometries	Straight, Knife, Claw, Barracuda	Straight, Knife, Claw, Barracuda, Curette
Operating Conditions	10 – 27°C 10% - 85% RH 70kPa – 106kPa	10 – 40°C 10% - 85% RH 70kPa – 106kPa

807.92(b)(1) – Nonclinical Testing to Support Submission

A suite of performance testing was executed to demonstrate substantial equivalence with the predicate devices. Testing included, but was not limited to:

- Reprocessing, sterilization, and package integrity testing per FDA Guidance documents and recognized standards
- Biocompatibility testing per FDA Guidance documents and recognized standards
- Software and wireless technology testing per FDA Guidance documents and recognized standards
- EMC and Electrical Safety testing per FDA recognized standards
- Bench testing per various internal protocols
- Simulated Use testing per various internal protocols
- Human Factors and Usability testing per FDA Guidance documents and recognized standards

807.92(b)(2) – Clinical Testing

No clinical testing was required to support this submission.

807.92(b)(3) – Conclusions Drawn from Testing Performed

Results of performance testing were determined successful for all protocols and demonstrate that the functionality, integrity, and safety and effectiveness of the Sonopet iQ Ultrasonic Aspirator System are sufficient for their intended use. Verification test results for the Sonopet iQ Ultrasonic Aspirator System confirm differences in technology raise no new issues of safety and effectiveness when compared to the predicate devices.

Conclusion/ Substantial Equivalence (SE) Rationale:

The subject device, in comparison with the legally marketed predicate, has the same intended use, indications for use, operating principles, energy source, and functional outputs. Performance testing and risk analysis demonstrate that the device is as safe and effective as the predicate device and does not raise different significant questions of safety and effectiveness.