March 24, 2025

Stryker Instruments
Louise Keane
Regulatory Affairs Manager
1941 Stryker Way
Portage, Michigan 49002

Re: K243930
Trade/Device Name: Sonopet iQ Ultrasonic Aspirator System (5500-050-000)
Regulatory Class: Unclassified
Product Code: LFL
Dated: December 20, 2024
Received: March 20, 2025

Dear Louise Keane:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.03.24 23:28:37 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243930

Device Name

Sonopet iQ Ultrasonic Aspirator System (5500-050-000)

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.

510(k) Summary

Submitter Information
Stryker Instruments
1941 Stryker Way,
Portage, MI 49002, USA

Contact Information
Leandra Burke
Staff Regulatory Affairs Specialist
Tel: (269)823-4639
Email: leandra.burke@stryker.com

Date: 20 December 2024

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

Predicate Device Details	
Trade / Proprietary Name	Sonopet iQ Ultrasonic Aspirator System
510(k)	K213824
Product Code	LFL
Manufacturer	Stryker Corporation

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.

Modifications to the device console software allow for inter-device communications with compatible Stryker devices, and the implementation of Stryker's proprietary communications protocol 'DCM' (Device Communication Module) to support these communications.

RISE (Reimagining Integrated Surgical Experience) is an optional software functionality that allows for ethernet-based communication between compatible Stryker devices (i.e., Connected OR Hub, SDC4K Information Management System (SDC4K), and CORE 2 consoles) and utilizes the DCM communications protocol.

The RISE functionality is built into the Sonopet iQ console software but can only be accessed via a Stryker-provided activation license.

RISE provides for an integrated OR (Operating Room) solution to healthcare facilities that simplifies workflows and reduces OR clutter. In a RISE configuration, adjustment of the Sonopet iQ power, suction, irrigation, and pulse control settings can now be made directly on the Connected OR Hub / SDC4K GUI, thereby allowing the user to input commands via a single console.

RISE functionality also features optional foot pedal assignment, which provides users the opportunity to use a single foot pedal to control multiple handpieces.

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.

Comparison of Technological Characteristics

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

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510(k) Summary

Feature	Subject device	Predicate device (K213824)	Assessment
Model/brand name	Sonopet iQ Ultrasonic Aspirator System	Sonopet iQ Ultrasonic Aspirator System	Identical
Classification	Unclassified	Unclassified	Identical
FDA Product code	LFL	LFL	Identical
Review Panel	General and Plastic Surgery	General and Plastic Surgery	Identical
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.	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.	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
Conditions of Use	Professional use only in a professional healthcare environment	Professional use only in a professional healthcare environment	Identical
Primary User Population	Trained Surgeon	Trained Surgeon	Identical
Patient Population	General	General	Identical
Control Mechanism Comparison			
Ultrasonic Energy	Piezo-electric, sinusoidal, non-continuous	Piezo-electric, sinusoidal, non-continuous	Identical
Irrigation	Forced, via peristaltic pump	Forced, via peristaltic pump	Identical
Aspiration (Suction)	Vacuum Pump	Vacuum Pump	Identical

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510(k) Summary

Feature	Subject device	Predicate device (K213824)	Assessment
Performance Specification Comparison			
Energy Source	AC powered from mains supply through detachable cord	AC powered from mains supply through detachable cord	Identical
Electrical classification	Class II	Class II	Identical
MR Safety	MR Unsafe	MR Unsafe	Identical
Technological Characteristics / Features Comparison			
Ultrasonic power delivery modes	Constant, variable	Constant, variable	Identical
Primary user interface	Graphical User Interface (GUI).	Graphical User Interface (GUI).	Identical
Energy activation method	Foot pedal	Foot pedal	Identical
System setting adjustment	Console GUI Hand Controller (optional) Compatible Stryker devices (via optional RISE functionality)	Console GUI Hand Controller (optional)	Equivalent – confirmed safe and effective.
LAN Communications	Ethernet Port – service, ethernet connection for RISE communications	Ethernet Port – service only	Equivalent – confirmed safe and effective.

Summary of Nonclinical Testing
The following testing was conducted to demonstrate that the modifications to the subject device are as safe and effective as the predicate:

- 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 testing per FDA guidance documents and recognized standards

Results of testing demonstrate the subject device to be substantially equivalent to the predicate device in terms of safety and effectiveness.

Clinical Testing
No clinical testing was required to support this submission.

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 console confirm differences in technology raise no new issues of safety and effectiveness when compared to the predicate device.

Conclusion
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 new or different questions of safety and effectiveness.