March 3, 2023

Stryker Corporation
Thomas Flannelly
Staff Regulatory Affairs Specialist
1941 Stryker Way
Kalamazoo, Michigan 49002

Re: K223770
Trade/Device Name: Sonopet 1Q 3 7cm 1Q Large
Regulatory Class: Unclassified
Product Code: LFL

Dear Thomas Flannelly:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 16, 2023. Specifically, FDA is updating this SE Letter to include the proper electronic signature as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Trumbore, OHT4: Office of Surgical and Infection Control Devices, (301)796-5436, mark.trumbore@fda.hhs.gov.

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.03 11:16:00 -05'00'

Mark Trumbore
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

February 16, 2023

Stryker Corporation
Thomas Flannelly
Staff Regulatory Affairs Specialist
1941 Stryker Way
Kalamazoo, Michigan 49002

Re: K223770
Trade/Device Name: Sonopet iQ 37cm iQ Large
Regulatory Class: Unclassified
Product Code: LFL
Dated: December 13, 2022
Received: December 15, 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,

On behalf of
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)*

Device Name
Sonopet iQ 37cm iQ Large

Indications for Use *(Describe)*
The 37cm iQ Large tip and sleeve sets, when used with the appropriate Sonopet iQ handpiece, are intended for use in surgical procedures where fragmentation, emulsification, and aspiration of tissue is desirable.

The 37cm iQ Large tip and sleeve sets intended for soft tissue may be used in surgical procedures including gastrointestinal and affiliated organ surgery, urological surgery, general 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6.0 Submitter Information

This Premarket Notification is submitted by:

Stryker Instruments
1941 Stryker Way
Portage
MI 49002-9711
USA

Contact Information

Thomas Flannelly
Staff Regulatory Affairs Engineer
Ph: 011-353-87-6487949
Email: Thomas.Flannelly@stryker.com
Date Prepared: 13 December 2022

6.1 Device Name

Table 6-1: Subject Device Information

Subject Device Information	
Trade/ Proprietary Name	Sonopet iQ 37cm iQ Large
Common Name	Sonopet iQ Laparoscopic Tip
Regulation Name	Aspirator, Surgical Ultrasonic
Review Panel	General and Plastic Surgery
Product Code	LFL
Regulatory Class	Unclassified

6.2 Predicate Device

The legally marketed predicate for the subject device is detailed in Table 6-2.

Table 6-2: Predicate Device Information

Predicate Device Name	Part Numbers	510(k)	Product Code	Manufacturer
Sonopet iQ 20cm iQ Standard	5500-25S-301	K213824	LFL	Stryker Instruments

6.3 Indications for Use

The 37cm iQ Large tip and sleeve sets, when used with the appropriate Sonopet iQ handpiece, are intended for use in surgical procedures where fragmentation, emulsification, and aspiration of tissue is desirable.

The 37cm iQ Large tip and sleeve sets intended for soft tissue may be used in surgical procedures including gastrointestinal and affiliated organ surgery, urological surgery, general 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 removal of uterine fibroids.

6.4 Device Description

The Sonopet iQ Ultrasonic Aspirator System is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, emulsifies fragments and removes unwanted tissue. The system consists of a console to provide control and power functions, a surgical handpiece to provide ultrasonic mechanical energy (25kHz), sixteen (16) tips with irrigation sleeves and a cassette for irrigation and suction. Users may choose from three different styles of foot pedals. The sixteen tips and sleeves consist of a soft tissue family and a hard tissue family.

The Sonopet iQ 37cm iQ Large (5500-25S-601) is the subject device of this submission and is an extension to the family of Sonopet iQ soft tissue tips and sleeves which are commercially available in the United States. The Sonopet iQ 37cm iQ Large is a single use device that forms part of the Sonopet iQ Ultrasonic Aspirator System.

The following primary modifications are made to Sonopet iQ 37cm iQ Large with respect to the predicate device:

- The dimensional specifications are longer than the predicate device. The subject device is 37cm in length and will be 17cm longer than the predicate device (20cm).
- The design dimensions and materials have undergone modifications to allow it to fit into a 5mm trocar.
- The subject device will not be indicated for neurosurgery, unlike the predicate device.
- In its packaging configuration, the subject device will have a single barrier while the predicate device has a double barrier.

6.5 Comparison of Technological Characteristics

The subject device has the same intended use as the predicate device. The Sonopet iQ 37cm iQ Large also shares the same indications as the predicate apart from the neurosurgery indication. They both have the same operating principals, control mechanisms, performance specifications and system interactions. They also share the same energy source and have a similar design. No new materials are introduced for the subject device in comparison to the predicate device, except for the Iron Oxide colorant used on the tips Silicone O-ring.

Risk evaluation and performance testing have shown that the differences between the predicate and subject devices do not introduce new issues of safety and effectiveness. The evaluation and testing have demonstrated that the subject device is substantially equivalent to the predicate device.

6.6 Summary of Non-Clinical Testing

A suite of non-clinical testing was executed to demonstrate substantial equivalence with the predicate device. Testing included:

- Sterilization and Package Integrity
- Biocompatibility
- EMC and Electrical Safety
- Design Verification
- Human Factors and Usability
- Simulated Use Validations

All pre-defined acceptance criteria for the above tests have been met. Results from this testing confirm that the subject device performs as intended and supports a determination of substantial equivalence to the predicate device.

6.7 Summary of Clinical Testing

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

6.8 Conclusion

The Sonopet iQ 37cm iQ Large is substantially equivalent to the predicate device currently cleared under K213824 as it has the same intended use, operating principles, and technological characteristics. The modifications introduced do not raise new questions of safety or effectiveness. Performance testing has demonstrated that the Sonopet iQ 37cm iQ Large is substantially equivalent to the predicate device.