



December 21, 2023

Gynesonics, Inc.
Diane King
VP, Global Regulatory Affairs and Healthcare Compliance
600 Chesapeake Drive
Redwood City, CA 94063

Re: K233848
Trade/Device Name: Sonata Transcervical Fibroid Ablation System 2.2
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar Endoscopic Coagulator-Cutter and Accessories
Regulatory Class: Class II
Product Code: KNF, ITX, IYO
Dated: December 1, 2023
Received: December 5, 2023

Dear Diane King:

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.

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.

Assistant Director

DHT3B: Division of Reproductive,

Gynecology and Urology Devices

OHT3: Office of GastroRenal, ObGyn,

General Hospital and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233848

Device Name

Sonata Transcervical Fibroid Ablation System 2.2

Indications for Use (Describe)

The Sonata Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

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.

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510(k) Summary

Applicant Name: Gynesonics, Inc.

Applicant Address: 600 Chesapeake Drive
Redwood City, CA 94063

Applicant Contact: Christine Ehmann
cehmann@gynesonics.com
(650) 241-6140

Date Prepared: December 21, 2023

Correspondent Name: Gynesonics, Inc.

Correspondent Address: 600 Chesapeake Drive
Redwood City, CA 94063

Correspondent Contact: Diane King
dking@gynesonics.com
(650) 216-3883

Device Information

Device Trade Name: Sonata Transcervical Fibroid Ablation System 2.2
(SONATA2-220)

Common Name: Sonography-Guided Transcervical Fibroid Ablation System

Classification Name: Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)

Regulation Number: 884.4160

Regulatory Class: II

Product Code: KNF, ITX, IYO

Legally Marketed Predicate Devices

510(k)	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222304	Sonata® Transcervical Fibroid Ablation System 2.2	KNF

Device Description:

The Sonata System 2.2 provides radiofrequency (RF) ablation of uterine fibroids using a transcervical approach that is uterine sparing without incisions or material uterine distension. The system enables a clinician to deliver radiofrequency energy to fibroid tissue resulting in thermal fixation and coagulative necrosis of the tissue.

The system combines two technologies - ultrasound for visualization, and radiofrequency energy for ablative therapy - in a single integrated handpiece.

The Sonata System is comprised of medical equipment, software, and various single-use and reusable instruments. A single-use Radiofrequency Ablation (RFA) Handpiece attaches to a reusable Intrauterine Ultrasound (IUUS) Probe to provide sonography-guided RF ablation. Once connected, the combination is referred to as the “Treatment Device”. The RFA Handpiece connects to the Sonata RF Generator and contains the Needle Electrodes that deliver radiofrequency energy to the target tissue. The IUUS Probe connects to the SMART Tablet and provides diagnostic ultrasound imaging and guidance. Ultrasound guidance is used to localize the fibroids from within the uterine cavity, guide placement of the RFA Handpiece Needle Electrodes into a target fibroid and ensure safety with respect to the serosa. When the Needle Electrodes are anchored within tissue, the physician is able to pivot the IUUS Probe transducer around the Needle Electrodes in order to confirm safety of the uterine serosa through multiple ultrasound planes.

The Sonata System allows for treatment planning through the use of a graphical interface and automated control of RF energy delivery.

Sonata Graphical Guidance Software (GGS) includes the SMART Guide and integrates treatment planning, targeting, and ablation of fibroids. The SMART Guide displays a real-time graphic overlay on the live ultrasound image for targeting and deployment of radiofrequency ablation.

Two main elements of the SMART Guide are the Ablation Zone and the Thermal Safety Border.

- Ablation Zone (red inner ellipse) – a two-dimensional representation of the outer boundary of the average region of tissue ablation for the selected ablation size
- Thermal Safety Border (green outer ellipse) – the distance at which tissue outside of the Ablation Zone is safe from the potential of thermal damage.

The change associated with this submission is an update to the Sonata Intrauterine Ultrasound (IUUS) Probe Instructions for Use to include an additional sterilization option.

Intended Use/Indications for Use

The Sonata® Transcervical Fibroid Ablation System 2.2 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

Indications for Use Comparison

The indications for use of the modified Sonata Transcervical Fibroid Ablation System 2.2 are identical to the indication of use of the predicate Sonata Transcervical Fibroid Ablation System 2.2.

Changes Triggering this 510(k)

Table 1 summarizes the changes to the Sonata System 2.2 that are driving the need for a new 510(k).

Table 1 Summary of Device Changes Triggering New 510(k)

Sonata System 2.2 Component/Accessory	Description of Change	Reason for change	Impact of Change
Sonata Intrauterine Ultrasound (IUUS) Probe IUSP-002	Labeling change: Addition of validated instructions for sterilization of the IUUS Probe by the following sterilization systems: STERRAD NX and STERRAD NX with ALLClear™ Technology.	Expand options for sterilization of reusable device.	Sterilization validation and verification of device compatibility required.

Technological Comparison

The modified Sonata Transcervical Fibroid Ablation System 2.2 has the same technological characteristics (design, material, principle of operation, energy source) as the predicate device Sonata Transcervical Fibroid Ablation System 2.2, K222304. The only difference between the modified and predicate device is the addition of STERRAD NX, STERRAD NX with ALLClear Technology, and STERRAD 100NX with ALLCLEAR Technology as alternate sterilization options for the Sonata Intrauterine Ultrasound Probe.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Gynesonics has applied their design control procedures including risk analysis to evaluate the modifications to the device which are the subject of this 510(k). The modifications in the subject device did not raise any new questions of safety and effectiveness.

For each change, verification and, as required, validation was conducted on the modified device to demonstrate that the modified device meets the applicable design requirements. Nonclinical tests and evaluations performed and relied upon to support a determination of substantial equivalence include sterilization validation, biocompatibility, product life, basic safety and essential

performance, and usability. The test methods and acceptance criteria used were established methods consisting of FDA recognized standards and/or the same methods and criteria as were used in the predicate device submission; thus meeting the FDA's requirement for eligibility for a Special 510(k). In all cases, the verification and validation testing met acceptance criteria. Therefore, the subject device is substantially equivalent to the predicate.