April 2, 2025

Gynesonics, Inc.
Christine Ehmann
Director of Regulatory Affairs
600 Chesapeake Drive
Redwood City, California 94063

Re: K250705
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: II
Product Code: KNF, ITX, IYO
Dated: March 7, 2025
Received: March 10, 2025

Dear Christine Ehmann:

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.

The FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR

807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Reginald K. Avery -S

for 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

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.

510(k) Number *(if known)*
K250705

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.

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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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: March 7, 2025

Correspondent Name: Gynesonics, Inc.

Correspondent Address: 600 Chesapeake Drive

Redwood City, CA 94063

Correspondent Contact: Christine Ehmann

cehmann@gynesonics.com

(650) 241-6140

Device Information

Device Trade Name: Sonata® Transcervical Fibroid Ablation System 2.2

Common Name: Sonography-Guided Transcervical Fibroid Ablation System

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

Regulation Number: 884.4160

Product Code: KNF, ITX, IYO

Legally Marketed Predicate Devices

510(k)	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K240503	Sonata Transcervical Fibroid Ablation System 2.2	KNF
The predicate device has not been subject to a design-related recall.		

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. The change associated with this submission regards a change to materials, labeling artwork, and cable length of the Sonata Dispersive Electrode.

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. Dispersive Electrodes are placed on the patient's thighs and connected to the RF Generator to complete the electrical circuit. 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.

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.

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, K240503. The only difference between the modified device and predicate device is a change to materials, labeling artwork, and cable length of the Sonata Dispersive Electrode.

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 biocompatibility, mechanical performance, product life, basic electrical safety and essential performance including electromagnetic compatibility. 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 a Special 510(k). In all cases, the verification and validation testing met acceptance criteria with and without justification. Therefore, the subject device is as safe and effective as the predicate device and supports a substantial equivalence determination.