November 8, 2022

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

Re: K222304
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: October 7, 2022
Received: October 11, 2022

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 (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,

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

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)*
K222304

Device Name
Sonata® Transcervical Fibroid Ablation System 2.2

Indications for Use *(Describe)*
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.

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

Sponsor: Gynesonics, Inc.

600 Chesapeake Drive

Redwood City, CA 94063

Contact Person: Diane King

VP Global Regulatory Affairs and Healthcare Compliance

dking@gynesonics.com

(650) 216-3883

Date Prepared: November 2, 2022

Device Information

Proprietary Name: Sonata® Transcervical Fibroid Ablation System 2.2

Common Name: Sonography-Guided Transcervical Fibroid Ablation System

Class: Class II

Regulation: 21 CFR 884.4160
Unipolar endoscopic coagulator-cutter and accessories

Product Code: KNF Coagulator-Cutter, Endoscopic, Unipolar (And Accessories)
ITX Transducer, Ultrasonic, Diagnostic
IYO Ultrasonic pulsed echo imaging system

Classification Panel: 85 – Obstetrical & Gynecological

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.

Predicate Devices

The predicate device is listed in Table 1. The predicate device is the unmodified Sonata Transcervical Fibroid Ablation System 2.2.

The predicate device has not been the subject of any design-related recalls.

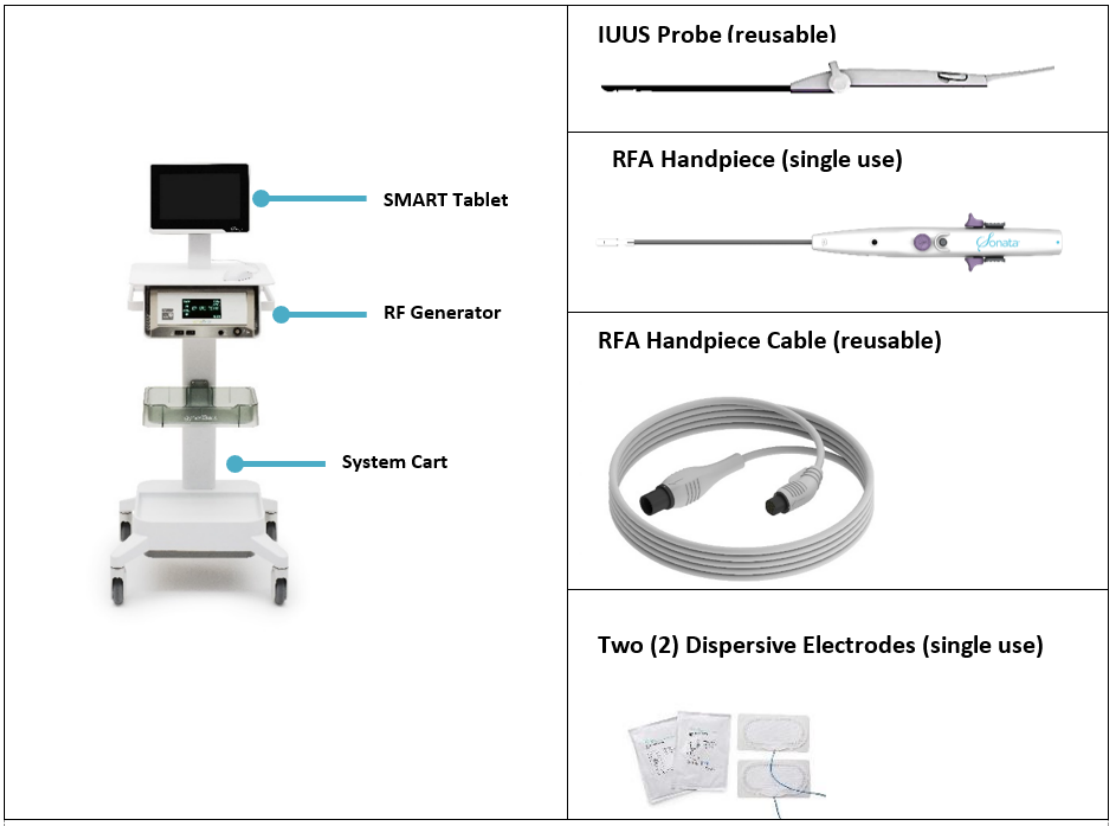
Table 1 Table of Predicate and Reference Device

510(k)	Product	510(k) Holder	Clearance Date
K211535	Sonata Transcervical Fibroid Ablation System 2.2	Gynesonics	June 17, 2021

Device Description:

The Sonata System 2.2 (Figure 1) 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.

Figure 1 Sonata System 2.2



The system combines two technologies - ultrasound for visualization, and radiofrequency energy for ablative therapy - in a single integrated handpiece (Figure 2).

Figure 2 Intrauterine Ultrasound (IUUS) Probe being connected to the Radiofrequency Ablation (RFA) Handpiece to form a single Treatment Device

The Sonata System is comprised of medical equipment (Figure 1), software, and various single-use and reusable instruments. Sonata System devices and accessories are summarized in Table 2. The devices that are changed or new with this submission are shown in **bold purple**.

Table 2 Sonata System 2.2 Devices and Accessories

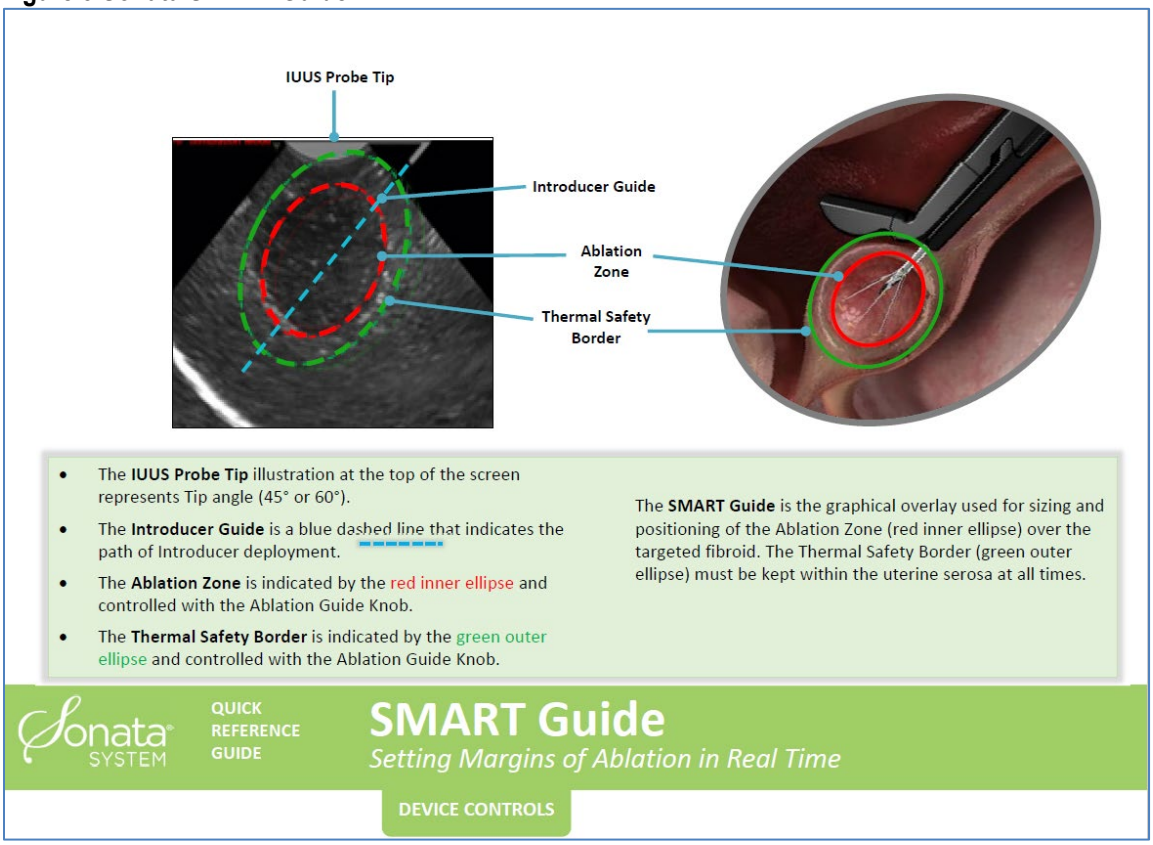
Catalog Number	Product Description
Durable Equipment	
SONATA2-110	Sonata Transcervical Fibroid Ablation System, consisting of:
RFG2-110	Sonata Radiofrequency Generator
USCON-2200	Sonata SMART Tablet
ACCY-002	Sonata System Cart
External components	*Footswitch, mouse, cables*
System Software	
SW-002	**Sonata System Software v2.1.2**
Reusable Devices	
IUSP-002	Sonata Intrauterine Ultrasound (IUUS) Probe (Non-Sterile) **(modified IFU)**
IUSP-002S	Sonata Intrauterine Ultrasound (IUUS) Probe (Sterile)
ACCY-008	Sonata RFA Handpiece Cable, Reusable
Single-Use Devices	
RFA-002	Sonata Radiofrequency Ablation Handpiece (Sterile)
DE-001	Sonata Dispersive Electrode (Non-sterile)
Accessories	
SHPR-001	Sonata Intrauterine Ultrasound Probe Sterile Shipper Kit
RTN-001	Sonata Intrauterine Ultrasound Probe Return Kit
ACCY-018	**Sonata IUUS Probe Connector Protector**
OM-1000-GS	Sonata IUUS Probe Reprocessing Tray (Manufacturer: Summit Medical LLC)
8EC4A	Endocavity Ultrasound Transducer (Manufacturer: Terason®)

A single-use Radiofrequency Ablation (RFA) Handpiece attaches to a reusable Intrauterine Ultrasound (IUUS) Probe as shown in Figure 2 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 (Figure 3) 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.

Figure 3 Sonata SMART Guide



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.

Changes triggering this 510(k)

Table 3 summarizes the changes to the Sonata System 2.2 that are driving the need for a new 510(k).

Table 3 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 liquid chemical sterilant processing systems: STERIS System 1E® (available in the US only) STERIS System 1® EXPRESS (available only OUS).	Expand options for sterilization of reusable device.	Sterilization validation and verification of device compatibility required.
Addition of unclassified accessory: ACCY-018 Sonata IUUS Probe Connector Protector Referenced within Sonata IUUS Probe IUSP-002 IFU	New accessory supports reprocessing of the IUUS Probe	Provides a water-tight cover for the IUUS Probe electrical connector during liquid reprocessing procedures.	Design controls were followed for the new accessory. See Table 5 for summary of design controls and test results relevant to use of the new accessories for reprocessing of the IUUS Probe.

Comparison to Predicate Device

Table 4 contains a detailed comparison of the modified Sonata System 2.2 to its predicate, the unmodified Sonata System 2.2. The modified Sonata Transcervical Fibroid Ablation System 2.2 employs the same fundamental scientific technology as the currently marketed predicate Sonata Transcervical Fibroid Ablation System 2.2 (K211535). The modifications in the subject device do not raise any new questions of safety and effectiveness.

Table 4 Substantial Equivalence Table for Sonata System

Characteristics	Modified Sonata System 2.2 (this submission)	Predicate Sonata System 2.2 (K211535)	Comparison Discussion
Intended Use/Indications for Use			
Intended Use	Ablation of uterine fibroids with diagnostic ultrasound imaging.	Ablation of uterine fibroids with diagnostic ultrasound imaging.	Same
Indications for Use	The Sonata System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.	The Sonata System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.	Same
Regulation Number	§884.4160 Unipolar endoscopic coagulator-cutter and accessories	§884.4160 Unipolar endoscopic coagulator-cutter and accessories	Same
Product Code	KNF Coagulator-Cutter, Endoscopic, Unipolar (And Accessories) ITX Transducer, Ultrasonic, Diagnostic IYO Ultrasonic pulsed echo imaging system	KNF Coagulator-Cutter, Endoscopic, Unipolar (And Accessories) ITX Transducer, Ultrasonic, Diagnostic IYO Ultrasonic pulsed echo imaging system	Same
System Functional/ Operational Features			
Principal Mode of Operation	Radiofrequency ablation of fibroid tissue resulting in thermal fixation and coagulative necrosis.	Radiofrequency ablation of fibroid tissue resulting in thermal fixation and coagulative necrosis.	Same
	B Mode ultrasound imaging	B Mode ultrasound imaging	Same
Primary user interface	Graphical user interface	Graphical user interface	Same

Characteristics	Modified Sonata System 2.2 (this submission)	Predicate Sonata System 2.2 (K211535)	Comparison Discussion
Treatment Planning	Integrated SMART Guide in software	Integrated SMART Guide in software	Same
Treatment Approach	In situ delivery and control of RF energy through deployable array needle electrodes with impedance and temperature feedback under visual control.	In situ delivery and control of RF energy through deployable array needle electrodes with impedance and temperature feedback under visual control.	Same
Treatment Guidance	Must be used under ultrasound guidance that is integrated into the system. The Ultrasound Console (SMART Tablet) with IUUS Probe is indicated for intrauterine imaging and guidance for placement of the Needle Electrodes.	Must be used under ultrasound guidance that is integrated into the system. The Ultrasound Console (SMART Tablet) with IUUS Probe is indicated for intrauterine imaging and guidance for placement of the Needle Electrodes.	Same
Route of Access	Transcervical	Transcervical	Same
System Components			
RF Generator	An RF Generator provides RF energy to the RFA Handpiece through the handpiece cable	An RF Generator provides RF energy to the RFA Handpiece through the handpiece cable	Same
Treatment Device	Single-use RFA handpiece with trocar-pointed shaft and 7 deployable needle electrodes, with reusable Cable. Combines with the reusable Intrauterine Ultrasound Probe to form the “Treatment Device”.	Single-use RFA handpiece with trocar-pointed shaft and 7 deployable needle electrodes, with single-use Cable. Combines with the reusable Intrauterine Ultrasound Probe to form the “Treatment Device”.	Same
Dispersive Electrodes	Dispersive Electrodes, quantity 2, with cables; provides return path for the RF energy delivered by the Handpiece	Dispersive Electrodes, quantity 2, with cables; provides return path for the RF energy delivered by the Handpiece	Same

Characteristics	Modified Sonata System 2.2 (this submission)	Predicate Sonata System 2.2 (K211535)	Comparison Discussion
Ultrasound Console	Incorporates the Terason uSmart3200T Ultrasound System (K150533) with addition of Sonata Graphical Guidance software. The uSmart3200T is a tablet with 11.6" LED backlit display, lithium-polymer battery. Uses a medical-grade power supply. Data transferred internally from the ultrasound engine to the laptop computer over a FireWire (aka IEEE 1394)	Incorporates the Terason uSmart3200T Ultrasound System (K150533) with addition of Sonata Graphical Guidance software. The uSmart3200T is a tablet with 11.6" LED backlit display, lithium-polymer battery. Uses a medical-grade power supply. Data transferred internally from the ultrasound engine to the laptop computer over a FireWire (aka IEEE 1394)	Same
Ultrasound Transducer	Gynesonics Sonata Intrauterine Ultrasound (IUUS) Probe	Gynesonics Sonata Intrauterine Ultrasound (IUUS) Probe	Same
Ultrasound Transducer	Claimed compatibility with commercially available Terason 8EC4A transducer	Claimed compatibility with commercially available Terason 8EC4A transducer	Same
Power cord	Power cord - A medical grade power cord that provides AC power to the power strip on the System Cart. The power strip in turn powers the RF Generator and the Ultrasound Console.	Power cord - A medical grade power cord that provides AC power to the power strip on the System Cart. The power strip in turn powers the RF Generator and the Ultrasound Console.	Same
Footswitch	Pneumatic footswitch with PVC tubing used to activate and terminate delivery of RF energy.	Pneumatic footswitch with PVC tubing used to activate and terminate delivery of RF energy.	Same
Optical Mouse	Optical Mouse	Optical Mouse	Same
System Cart	Cart, accommodates tablet	Cart, accommodates tablet	Same
Materials			
Materials – Patient Contact – IUUS Probe	Glass fiber filled polyetherimide, glass reinforced vinyl ester, fluorocarbon rubber, UV adhesive, Silicone	Glass fiber filled polyetherimide, glass reinforced vinyl ester, fluorocarbon rubber, UV adhesive, Silicone	Same
Patient Contact Materials – active electrode	Medical grade metal alloys and plastic polymers (i.e. Nitinol®, surgical grade stainless steel)	Medical grade metal alloys and plastic polymers (i.e. Nitinol®, surgical grade stainless steel)	Same

Characteristics	Modified Sonata System 2.2 (this submission)	Predicate Sonata System 2.2 (K211535)	Comparison Discussion
Patient Contact Materials - dispersive electrode	Acrylate-polymer based hydrogel, polyester fabric with poly film and medical grade acrylic adhesive	Acrylate-polymer based hydrogel, polyester fabric with poly film and medical grade acrylic adhesive	Same
Biocompatibility	Is biocompatible with intended use in compliance with • ISO 10993-1 5th Ed. 2018-08 • ISO 10993-5 3rd ed. 2009-06-01 • ISO 10993-10 3rd ed. 2010-08-01 • ISO 10993-11 3rd ed. 2017-09	Is biocompatible with intended use in compliance with • ISO 10993-1 5th Ed. 2018-08 • ISO 10993-5 3rd ed. 2009-06-01 • ISO 10993-10 3rd ed. 2010-08-01 • ISO 10993-11 3rd ed. 2017-09	Same
Safety and Performance			
Electrical Safety & EMC	ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009 / (R)2012 And A2:2010/(R)2012 IEC 60601-1-2 Ed 4: 2014-02 IEC 60601-1-6 Ed 3.1 2013-10 ANSI AAMI IEC 62366-1:2015 IEC 60601-1-8: Edition 2.1 2012-11 ANSI/AAMI IEC 60601-2-2:2017 IEC 60601-2-37 Ed 2.1 2015 IEC 62304 Ed. 1.1 2015-06	ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009 / (R)2012 And A2:2010/(R)2012 IEC 60601-1-2 Ed 4: 2014-02 IEC 60601-1-6 Ed 3.1 2013-10 ANSI AAMI IEC 62366-1:2015 IEC 60601-1-8: Edition 2.1 2012-11 ANSI/AAMI IEC 60601-2-2:2017 IEC 60601-2-37 Ed 2.1 2015 IEC 62304 Ed. 1.1 2015-06	Same
Performance testing – System level (bench)	• Shelf-life / Service life • Confirmatory verification to specifications, standards, and guidance documents.	• Shelf-life / Service life • Confirmatory verification to specifications, standards and guidance documents.	Same including design controls

Characteristics	Modified Sonata System 2.2 (this submission)	Predicate Sonata System 2.2 (K211535)	Comparison Discussion
Performance testing – Ablation	• Ablation output • RF Generator safety features • Handpiece retention forces • Ultrasound visibility of the handpiece • Dispersive Electrode adhesion • RF Generator software and hardware verification and validation, including GUI, alerts, communication between components, real-time feedback to user via device sensors, power control, and software/hardware interface Successfully demonstrated through early clinical and bench ablation testing that the system performs as intended and per specifications. Ablation capability was confirmed and the radiofrequency ablation provides a reproducible, discretely demarcated zone of tissue necrosis.	• Ablation output • RF Generator safety features • Handpiece retention forces • Ultrasound visibility of the handpiece • Dispersive Electrode adhesion • RF Generator software and hardware verification and validation, including GUI, alerts, communication between components, real-time feedback to user via device sensors, power control, and software/hardware interface Successfully demonstrated through early clinical and bench ablation testing that the system performs as intended and per specifications. Ablation capability was confirmed and the radiofrequency ablation provides a reproducible, discretely demarcated zone of tissue necrosis.	Same
Acoustic Output Measurement Standard	NEMA UD 2-2004 (R2009) IEC 60601-2-37 Ed 2.1 2015	NEMA UD 2-2004 (R2009) IEC 60601-2-37 Ed 2.1 2015	Same
Acoustic Output Global Maximum B Mode:	• I_{SPTA} ≤ limit of 720 mW/cm^2 Value: 162 mW/cm^2 • MI ≤ limit of 1.9 Value: 1.7	• I_{SPTA} ≤ limit of 720 mW/cm^2 Value: 162 mW/cm^2 • MI ≤ limit of 1.9 Value: 1.7	Same

Characteristics	Modified Sonata System 2.2 (this submission)	Predicate Sonata System 2.2 (K211535)	Comparison Discussion
Usability and Human Factors Validation	IEC 60601-1-6 Ed 3.1 2013-10 ANSI AAMI IEC 62366-1:2015 The modified Sonata System 2.2 continues to rely on HFE validation of Sonata System 2.1.	IEC 60601-1-6 Ed 3.1 2013-10 ANSI AAMI IEC 62366-1:2015 Sonata System 2.2 continues to rely on HFE validation of Sonata System 2.1.	Same
Clinical Trial to demonstrate safety and effectiveness	IDE G140114 NCT NCT02228174 n = 147 22 centers with treated patients Single-arm cohort study with each subject serving as her own control. The modified Sonata System 2.2 continues to rely on the same clinical trial study as the unmodified Sonata System 2.2. The changes associated with the subject of this 510k do not change safety or efficacy of the device.	IDE G140114 NCT NCT02228174 n = 147 22 centers with treated patients Single-arm cohort study with each subject serving as her own control. Sonata System 2.2 continues to rely on the clinical trial study as Sonata System 2.1.	Same

Performance Testing

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). 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. The test methods and acceptance criteria used established methods consisting of FDA recognized standards and/or the same methods and criteria as were used in the predicate device submission. Table 5 summarizes the design control activities. In all cases, the verification and validation testing met the acceptance criteria.

Table 5 Summary of Design Control Activities

Change	Summary of Design Control Activities and Testing
Addition of validated instructions for sterilization of the IUUS Probe by STERIS System 1E liquid chemical processing system for Reusable Sonata Intrauterine Ultrasound (IUUS) Probe IUSP-002	Risk Analysis Sterilization Validation Residuals Testing Impact on IUUS Probe Use Life Impact on IUUS Probe Biocompatibility Impact on Human Factors Engineering analysis Electrical safety certification
New Accessory for reprocessing, IUUS Probe Connector Protector	Risk Analysis Design verification Connector Protector Life testing including shipping stress & multiple cycles of simulated use, cleaning, disinfection & sterilization with IUUS Probe Human Factors Engineering Analysis

The risk analysis demonstrated that no new risks were identified as a consequence of the modifications and the overall risk profile of the device remains unchanged.

Animal Data

No animal data was needed to validate the subject modified Sonata System 2.2.

Clinical Data

No additional clinical study data was needed to validate the subject modified Sonata System 2.2.

Conclusion

The subject modified Sonata Transcervical Fibroid Ablation System 2.2 employs the same fundamental scientific technology as the currently marketed predicate Sonata Transcervical Fibroid Ablation System 2.2 (K211535). Both systems combine radiofrequency ablation with intrauterine sonography. The indications for use and workflow are the same. The modifications to the device, as described in this 510(k) have been verified and validated according to design controls. The changes in the subject device did not raise any new questions of safety and effectiveness. Therefore, the Sponsor believes that the modified Sonata System 2.2 is substantially equivalent to its predicate device, the Sonata System 2.2 (K211535).