May 4, 2020

Gynesonics, Inc.
Diane King
VP Regulatory Affairs and Quality Assurance
600 Chesapeake Drive
Redwood City, CA 94063

Re: K193516
Trade/Device Name: Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar Endoscopic Coagulator-Cutter and Accessories
Regulatory Class: II
Product Code: KNF, ITX, IYO
Dated: March 31, 2020
Received: April 1, 2020

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, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193516

Device Name

Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1

Indications for Use *(Describe)*

The Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1 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 Regulatory Affairs and Quality Assurance

dking@gynesonics.com

(650) 216-3883

Date Prepared: April 30, 2020

Device Information

Proprietary Name:	Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1
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

Indications for Use

The Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

Predicate Devices

The predicate and reference devices are listed in Table 1. The predicate device is the Sonata® Sonography-Guided Transcervical Fibroid Ablation System. The Terason™ uSmart3200T Ultrasound System, which is the ultrasound engine incorporated into the Sonata® System 2.1, is a reference device.

Neither the predicate nor the reference device has been subject to design-related recalls.

Table 1 Table of Predicate and Reference Device

510(k)	Product	510(k) Holder	Clearance Date
K173703	Sonata® System	Gynesonics	August 15, 2018
K150533	Terason™ uSMART3200T Ultrasound System	Teratech Corporation	May 9, 2015

Device Description:

The Sonata® System 2.1 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. The system combines two technologies - ultrasound for visualization, and radiofrequency energy for ablative therapy - in a single integrated handpiece. The Sonata® System 2.1is comprised of medical equipment (Figure 1), software, and various single-use and reusable instruments. Sonata® System 2.1 devices and accessories are summarized in Table 2.

Figure 1 Sonata® System 2.1

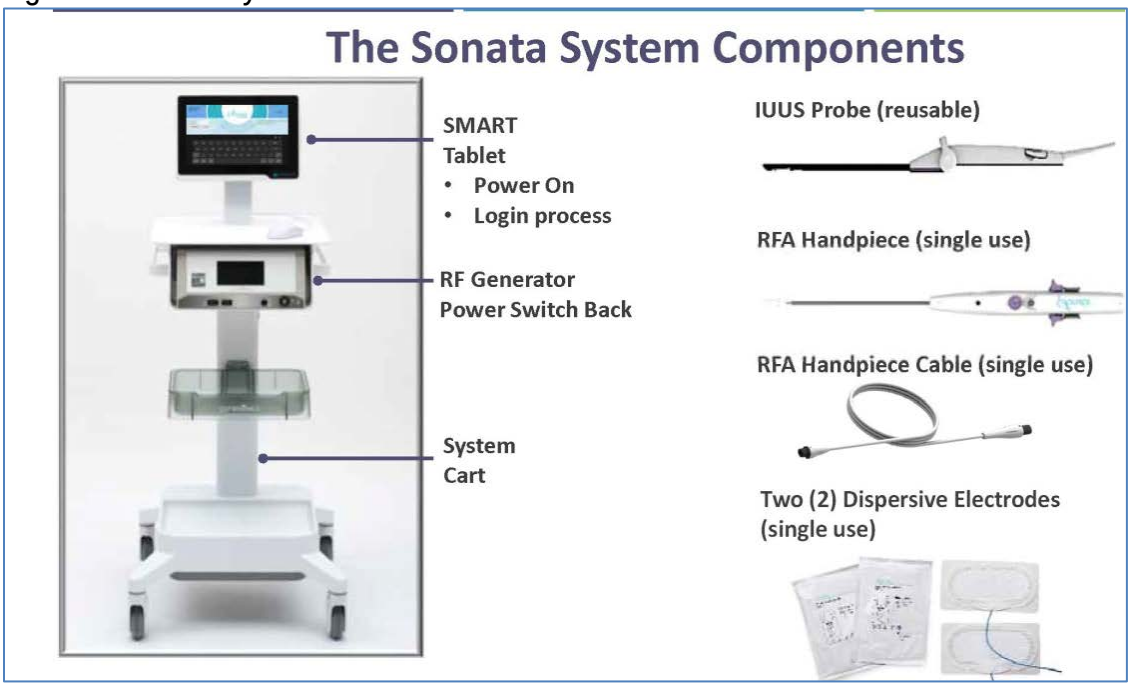


Table 2 Sonata® System 2.1 Devices and Accessories

Catalog Number	Product Description
Durable Equipment	
SONATA2-110	Sonata® Sonography-Guided Transcervical Fibroid Ablation System, consisting of:
RFG2-110	Sonata® Radiofrequency Generator
USCON-2200	Sonata® SMART Tablet
ACCY-002	Sonata® System Cart
Component kit and Instructions for Use	*Footswitch, mouse, cables, and instructions for use.*
System Software	
SW-002	Sonata® System Software
Reusable Devices	
IUSP-002	Sonata® Intrauterine Ultrasound (IUUS) Probe (Non-Sterile)
IUSP-002S	Sonata® Intrauterine Ultrasound (IUUS) Probe (Sterile)
Procedure Pack with Single-Use Devices	
PRO\KIT-001	Sonata® Procedure Kit; *contains:*
RFA-002	Sonata® Radiofrequency Ablation Handpiece quantity 1, sterile
ACCY-007	Sonata® RFA Handpiece Cable, Single-use
DE-001	Sonata® Dispersive Electrode quantity 2, non-sterile
Accessories	
SHPR-001	Sonata® Intrauterine Ultrasound Probe Sterile Shipper Kit
CYL-001	Sonata® IUUS Probe Soaking Cylinder
RTN-001	Sonata® Intrauterine Ultrasound Probe Return Kit

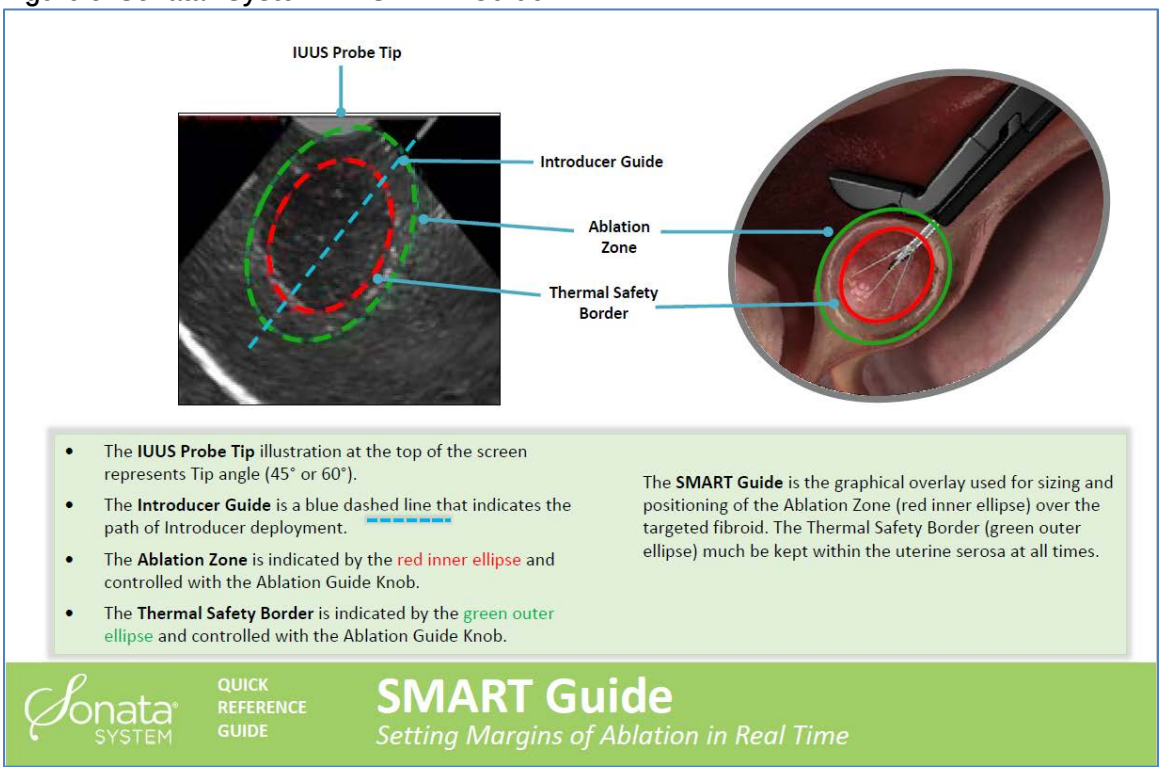
A single-use Radiofrequency Ablation (RFA) Handpiece attaches to a reusable Intrauterine Ultrasound (IUUS) Probe as shown in Figure 2 to provide sonography-guided RF ablation. Once connected, the combination is referred to as the "Treatment Device". The RFA Handpiece connects to the Sonata® RF Generator 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.

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

The Sonata® System 2.1 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). GGS 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® System 2.1 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 should not suffer thermal damage.

Comparison to Predicate Device

The Sonata® System 2.1 employs the same fundamental scientific technology as the currently marketed predicate Sonata® System (K173703). Both systems combine radiofrequency ablation with intrauterine sonography. The indications for use and workflow are the same. The primary differences are the implementation of the updated RFA Handpiece with joystick (SMART Control), Confirm Button, modified position sensors, and corresponding updates to the Graphical Guidance Software (GGS) to support these changes. Minor additional updates to the Sonata® System 2.1 include routine updates to the incorporated ultrasound console engine to the latest model which is in a tablet format, improvements in the IUUS Probe and changes to the Sonata® cart to accommodate the use of the tablet instead of a laptop.

Table 3 contains the discussion of similarities and differences between the subject device system and the predicate device. The comparison is organized by subsections covering intended use / indications for use, system function and features, components and materials, technical characteristics related to RF ablation, technical characteristics related to ultrasound, safety and performance testing, treatment planning and usability, and clinical testing.

Table 3 Substantial Equivalence Table for Sonata® System 2.1

Characteristics	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
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® Sonography-Guided Transcervical Fibroid Ablation System 2.1 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.	The Sonata® Sonography-Guided Transcervical Fibroid Ablation 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	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
Treatment Planning	Integrated SMART Guide in software	Integrated SMART Guide in software	Similar The SMART Guide has been updated to work with updated treatment device. There is no change to core software algorithms, target treatment temperature, or overall workflow.
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 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	Similar RF Generator has been updated for compatibility with the updated treatment device. There is no change to the control of RF energy delivery or other functionality.

Characteristics	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
Treatment Device	Single-use handpiece with trocar-pointed shaft and 7 deployable needle electrodes, with Cable. Combines with the reusable Intrauterine Ultrasound Probe to form the "Treatment Device".	Single-use handpiece with trocar-pointed shaft and 7 deployable needle electrodes, with cable. Combines with the reusable Intrauterine Ultrasound Probe to form the "Treatment Device".	Similar The RFA Handpiece design has been updated to provide a joystick (SMART Control), Confirm Button, and Introducer and Needle Electrode carriage position sensors instead of an Ablation Guide Knob and mechanical stops. The RFA Handpiece Cable is now a separate accessory that is connected to the RFA Handpiece. The same functionality and workflow is supported. Changes in device design were validated for usability in summative usability study.
Dispersive Electrodes	Dispersive Electrodes, quantity 2, with cables; provides return path for the RF energy delivered by the Handpiece	Dispersive Electrodes, quantity 2, and cables; provides return path for the RF energy delivered by the Handpiece	Same
Ultrasound Console	Incorporates the Terason uSmart3200T Ultrasound System 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 t3200 Ultrasound System with addition of Sonata® Graphical Guidance software. The t3200 is a laptop-based system with 15" 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)	Similar Subject device incorporates a more recent ultrasound system model, cleared under the reference device (K150533), to replace the ultrasound system model no longer available from supplier. Ultrasound functionality is not changed with the change to the tablet.
Ultrasound Transducer	Gynesonics Sonata® Intrauterine Ultrasound (IUUS) Probe	Gynesonics Sonata® Intrauterine Ultrasound (IUUS) Probe	Similar IUUS Probe updated with modifications for improved durability through change of materials and mechanical design. Increased number of transducer channels for incremental improvement in image quality and field of view. Changes were evaluated through performance and biocompatibility testing.

Characteristics	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
Ultrasound Transducer	Claimed compatibility with commercially available Terason 8EC4A transducer	No claim of compatibility with Terason 8EC4A transducer	Different The reference device K150533 includes the Terason uSmart3200T system with the Terason 8EC4A transducer. The Sonata® System 2.1 incorporates the uSmart3200T. The Sonata® Graphical Guidance Software (GGS) replaces the uSmart3200T user interface. GGS does not modify ultrasound image frames coming from the uSmart3200T. Terason 8EC4A transducer compatibility was evaluated with software, performance, and electrical testing.
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. All meet applicable electrical safety standards.
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 laptop	Similar Cart for subject device modified to accommodate different form factor of ultrasound console with a tablet instead of a laptop. Ability to adjust viewing angle of the tablet eliminates need for adjustment of cart height. The changes have no impact on safety or effectiveness.

Characteristics	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
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, transparent film, epoxy filler.	Similar Minor changes in materials for improved durability. Patient-contacting materials were demonstrated to be biocompatible for its intended use
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)	Similar Minor changes in materials for improved durability. Patient-contacting materials were demonstrated to be biocompatible for its intended use
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 • ISO 10993-12 4th ed. 2012-07-01	Is biocompatible with intended use in compliance with • ISO 10993-1 4th Ed. 2009-10-15 • ISO 10993-5 3rd ed. 2009-06-01 • ISO 10993-10 3rd ed. 2010-08-01 • ISO 10993-11 2nd ed. 2006-08-15 • ISO 10993-12 4th ed. 2012-07-01	Same with use of current standards version
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 3: 2007-03 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 60601-2-2:2009 IEC 60601-2-37 Ed 2.0 2007 IEC 62304 Ed. 1.1 2015-06	Same with current standards version

Characteristics	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
Performance testing – System level (bench)	• Shelf-life / Service life • Full system verification to specifications, standards, and guidance documents.	• Shelf-life / Service life • Full system verification to specifications, standards, and guidance documents.	Same
Performance testing – Ablation	• Confirmatory Ablation dimensions • Handpiece retention forces • Ultrasound visibility of the handpiece • 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	• 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	Different Performance testing was conducted on components modified from the predicate device. Performance testing data presented in K173703 remains applicable to unchanged components of the subject device.
(continued)	Successfully demonstrated through 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.	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.	Modifications to subject device did not require new clinical data. Clinical data presented in K173703 remains applicable to the subject device.
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 2.0 2007	Same with more recent standard version
Acoustic Output Global Maximum B Mode:	• I_{SPTA} ≤ limit of 720 mW/cm^2 Value: 72.5 mW/cm^2 • MI ≤ limit of 1.9 Value: 1.2	• I_{SPTA} ≤ limit of 720 mW/cm^2 Value: 162 mW/cm^2 • MI ≤ limit of 1.9 Value: 1.7	Similar Modifications to the subject device changed the acoustic output. The subject device output continues to meet the established acceptance criteria.

Characteristics	Sonata® System 2.1 (this submission)	Sonata® System K173703	Comparison Discussion & reference device
Usability and Human Factors Validation	IEC 60601-1-6 Ed 3.1 2013-10 ANSI AAMI IEC 62366-1:2015 HFE validation conducted in accordance with FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices* (Feb 3, 2016) successfully completed for treatment tasks.	IEC 60601-1-6 Ed 3.1 2013-10 ANSI AAMI IEC 62366-1:2015 HFE validation conducted in accordance with FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices* (Feb 3, 2016) successfully completed for treatment and reprocessing tasks.	Similar Changes in device design and software user interface were validated for usability in summative usability study.
Clinical Trial to demonstrate safety and effectiveness	N/A.	IDE G140114 NCT NCT02228174 n = 147 22 centers with treated patients Single-arm cohort study with each subject serving as her own control.	Different Modifications to subject device did not require new clinical data. Clinical data presented in K173703 remains applicable to the subject device.

Performance Testing

The Sonata® System 2.1 has been designed and developed under design controls. The Gynesonics' design controls incorporate risk management in compliance with ISO 14971. The product specifications for the individual device components and the integrated system have been verified and validated in a series of bench studies appropriate to the nature and risk of the changes. Table 4 summarizes the bench testing that supports the development and validation of the SMART Guide, as well as performance characteristics of the individual devices and of the integrated system. Applicable testing completed on the predicate device (noted Sonata® System in Table 4) is included for completeness. The testing completed on the predicate device is applicable for device components, specifications, or parameters that were unchanged or unaffected by the modifications in the subject device. Data leveraged from the predicate device is identified in the table below.

Table 4 Sonata® System 2.1 Performance Testing – Bench

Aspect	Item / Model Number	Test	Test Methodology	Results	Leveraged Data from Sonata® System K173703
SMART Guide Development and Validation	Sonata® System	Volumetric Ablation Registration	*Ex vivo* testing with bovine tissue to measure the volumetric registration offset in axes parallel and perpendicular to the Introducer.	Volume of ablation zone created by RFA Handpiece demonstrated to remain in fixed position relative to Introducer tip; thus, relative to ultrasound image of Introducer tip	Yes
		Development of the SMART Guide	*Ex vivo* testing with non-perfused bovine tissue model used to develop the Graphical Guidance Software SMART Guide in Ablation Zone (AZ) and Thermal Safety Border (TSB) dimensions. *In vivo* peri- and pre-Hysterectomy studies data also used to set final SMART Guide dimensions.	Initial dimensions of AZ and TSB developed from *ex vivo* bench ablation data. *In vivo* peri- and pre-hysterectomy studies were used to establish final dimensions of AZ and TSB.	Yes
	Sonata® System 2.1	Confirmatory Ablation Dimensions	E*x vivo* ablation dimensions were measured with a non-perfused bovine tissue model in study to confirm continued that SMART Guide remains applicable to Sonata® System 2.1.	When tested with the Sonata® System 2.1, dimensions of ablations produced in an *ex vivo* non-perfused bovine tissue model are consistent with the established AZ and TSB.	No
		Effect of Parameter Variations on Ablation Dimensions -			
	Sonata® System	Variation in Tissue Parameters	Finite Element Method (FEM) Computational Modeling to determine sensitivity of ablation dimensions to variations in tissue parameters.	Modeling demonstrates *ex vivo* non-perfused tissue model is conservative model to establish AZ and TSB. Modeling predicts that ablations performed within expected tissue variations *in vivo* remain within TSB.	Yes
		Variation in Treatment Temperature	*Ex vivo* testing with non-perfused bovine tissue model at 95 to 115°C to measure ablation dimensions.	Variations or errors in treatment temperature of +/-10°C from target would not result in ablation exceeding TSB at 95% confidence with 95% reliability.	Yes

Aspect	Item / Model Number	Test	Test Methodology	Results	Leveraged Data from Sonata® System K173703
		Variation in RF Power	*Ex vivo* testing with non-perfused bovine tissue model at maximum RF power for full ablation duration with 3 treatment sizes to measure ablation dimensions.	Variations or errors in RF output power including running at maximum power would not result in ablation exceeding TSB at 95% confidence with 95% reliability.	Yes
		Variation in Treatment Duration	*Ex vivo* testing with non-perfused bovine tissue model at 2x durations for 3 treatment sizes to measure ablation dimensions.	Variations or errors in setting or control ablation duration to 2X, or multiple ablations in the same tissue, would not result in ablation exceeding TSB at 95% confidence with 95% reliability.	Yes
Ultrasound Performance	Sonata® System 2.1	Determination of Ultrasound Parameters	Small part phantom model and beam profile & slice thickness phantom model to measure spatial resolution, contrast resolution, image penetration, and assess image slice thickness.	Ultrasound parameters for Sonata® IUUS Probe when used with the Sonata® Ultrasound Console were measured and tabulated for labeling and found sufficient for intended use.	No
		Acoustic Output	Type testing of acoustic measurements according to IEC 60601-2-37 and FDA guidance.	MI = 1.2 which is under regulatory limit of 1.9. I_{SPTA} = 72.5 mW/cm^2 which is under regulatory limit of 720 mW/cm^2. Acoustic Output table completed per FDA guidance based on measurements made.	No
		Ultrasound Clinical Measurement Accuracy	Software unit testing on every software build of accuracy of linear measurements using a small parts ultrasound phantom.	Sonata® System 2.1 meets stated product specification for ultrasound clinical measurement accuracy.	No
Design Verification Testing - Individual Device	System Cart ACCY-002	Verification to Specifications	Type testing of System Cart for design requirements not covered in system testing per IEC 60601-1	Sonata® System 2.1 Cart meets stated its product specifications.	No
	RF Generator RFG2-110	Verification to Specifications	Type testing of RF Generator per IEC 60601-1 and 60601-2-2 and verification of hardware specifications.	Sonata® RF Generator meets applicable hardware product specifications.	No

Aspect	Item / Model Number	Test	Test Methodology	Results	Leveraged Data from Sonata® System K173703
	Ultrasound Console USCON-2200	Verification to Specifications	Verification that the Ultrasound Console meets design requirements set forth in the product specification document is performed under varying verification tests, including Sonata® System 2.1 Integration, IUUS Probe functional testing, Acoustic Output, and Software testing.	In total, the combined testing demonstrates that the Sonata® Ultrasound Console meets applicable product specifications.	No
	IUUS Probe IUSP-002	Verification to Specifications	Following multiple cycles of cleaning, disinfection, sterilization, and simulated use, functional and mechanical aspects of IUUS Probes were tested.	Sonata® IUUS Probe meets its design requirements for functionality and mechanical aspects following multiple cycles of cleaning, disinfection, sterilization and simulated use.	No
	IUUS Probe IUSP-002S	Verification to Specifications	Verification that the sterile IUUS Probe meets requirements for functionality after sterilization is addressed in Section 14.3	Refer to the Sterilization/Shelf Life/Cleaning section below	No
	Sterile Shipper Kit SHPR-001	Verification to Specifications	Verification of physical requirements of shipper by inspection.	Sterile Shipper Kit meets its physical requirements.	Yes
Design Verification Testing - Individual Device (continued)	RFA Handpiece RFA-002	Verification to Specifications	Following EO sterilization, accelerated aging, climatic conditioning and simulated transit, RFA handpieces were tested for ablation performance, mechanical strength, electrical attributes and patient interface.	Sonata® RFA Handpiece meets its design requirements for ablation performance, mechanical strength, electrical attributes and patient interface following Gamma sterilization, accelerated aging, climatic conditioning and simulated transit.	No
	Dispersive Electrodes DE-001	Verification to Specifications	Verification that the Dispersive Electrode meets the key design requirements related to conductivity and adhesion after transit, and after a 3-year shelf life, is addressed in the Sterilization/Shelf Life/Cleaning section below.	Refer to the Sterilization/Shelf Life/Cleaning section below	Yes
		Need for Thermal Monitoring of Dispersive Electrodes	Scientific rationale and *in vivo* data from earlier device generations with integrated thermocouples in DE to justify removal of thermocouples from DE	Results demonstrate that DE does not require integrated thermocouples to prevent patient harm.	Yes

Aspect	Item / Model Number	Test	Test Methodology	Results	Leveraged Data from Sonata® System K173703
	Return kit for IUUS Probe RTN-001	Verification to Specifications	Verification of design requirements of return kit by inspection and drop testing (for leakage) to IATA regulation.	IUUS Probe Return Kit complies with IATA regulation and its design requirements.	Yes
	IUUS Probe Soaking Cylinder CYL-001	Verification to Specifications	Verification of design requirements of Soaking Cylinder by inspection and measurements.	Sonata® IUUS Probe Soaking Cylinder meets its design requirements.	Yes
Design Verification Testing - Integrated System	Sonata® System 2.1	Verification to Specifications	Following sterilization, accelerated aging and transit challenges for RFA Handpieces, multiple RFA Handpieces were combined with three IUUS Probes and one durable equipment system for functional integration testing including mechanical forces for connections, removals, and ability withstand loads, functional testing (multiple ablations), angle accuracy, and mechanical measurements of Treatment Device during simulated use.	Sonata® System 2.1 meets its system level design requirements.	No
		Operating Conditions			
		Temperature / Relative Humidity / Altitude	Type testing; functional testing of system across specified environmental conditions.	Sonata® System 2.1 meets all acceptance criteria across range of specified system operating conditions.	No
		Human Factors (HF) Evaluation			

Aspect	Item / Model Number	Test	Test Methodology	Results	Leveraged Data from Sonata® System K173703
		Human Factors – Treatment	15 Gynecologists representative of typical users involved with performing RFA for fibroids and impacted by device changes participated in a HF study following manufacturer's provided training and training decay period. Participants conducted one un-aided simulated ablation.	HF summative testing for treatment with the Sonata® System 2.1 validated that the Sonata® System and its labeling and training are safe and effective with respect to user interface, and usable for its intended users and use contexts.	No
	Sonata® System	Human Factors – Reprocessing	Testing was completed on the predicate device and minor changes did not necessitate retesting with the subject device. 15 Reprocessing technicians representative of typical users involved with performing reprocessing tasks (cleaning and sterilization) of devices participated in a HF study following training and training decay period. Participants performed unaided simulated reprocessing using IUUS Probe.	HF summative testing for reprocessing validated that the Sonata® System 2.1 and its labeling and training are safe and effective with respect to user interface, and usable for its intended users and use contexts with regard to reprocessing the reusable IUUS Probe.	Yes
Compatibility with Commercially Available Transducer	Terason 8EC4-A	Summary of Supporting Evidence	The Terason 8EC4A probe with the uSmart3200T ultrasound system is cleared under K150533. Additional EMC and functional testing performed with the 8EC4A probe connected to the SMART Tablet is performed to support a claim of compatibility.	Compatibility of the Terason 8EC4A probe with the Sonata® System 2.1 is established. The Sonata® System 2.1 complies with all applicable medical electrical safety and electromagnetic compatibility requirements when connected with the Terason 8EC4A probe, and the 8EC4A probe continues to function as intended.	No

Sterilization/Shelf Life/Cleaning

The sterilization methods for the Sonata® System 2.1 device components provided sterile – the Radiofrequency Ablation (RFA) Handpiece, RFA Handpiece Cable, and loaner sterile IUUS Probes packaged in the Sterile Shipper Kit - have been validated for sterilization efficacy and acceptable sterilant residuals according to:

- Selection of SAL — ANSI/AAMI ST67:2011(R2017)
- Microbiological aspects, EO — AAMI TIR16:2017
- Validation of Sterilization by EO — ISO 11135:2014
- Ethylene Oxide Sterilization Residuals — ISO 10993-7:2008(R2012) with Technical Corrigendum 1

Recommended cleaning and sterilization methods described in applicable Instructions for Use for the reusable Sonata® System 2.1 device component – the Sonata® Intrauterine Ultrasound (IUUS) Probe – have been validated for sterilization efficacy and acceptable sterilant residuals. The associated packaging including Sterile Shippers have been validated to demonstrate that the packaging can maintain the sterile barrier through the required shelf life and transit stress. The packaging of the Sonata® System 2.1 device components provided non-sterile, single use and with patient contact – the Dispersive Electrode (DE) – has been validated for its ability to protect over shelf life and transit stress. The packaging for the Sonata® System 2.1 device components provided not sterile and without patient contact have been validated for distribution and transit stress. Validation has been performed according to:

- Validation of Sterilization by EO — ISO 11135:2014
- Ethylene Oxide Sterilization Residuals — ISO 10993-7:2008
- Packaging for terminally sterilized devices — ISO 11607-1:2006/A1:2014
- Packaging Performance — ASTM D4169-16
- Seal Integrity — ASTM F1886/F1886M-16
- Accelerated Aging — ASTM F1980-16
- Package Integrity, Internal Pressurization — ASTM F2096-11
- Seal Strength — ASTM F88/F88M-15
- Conditioning — ASTM D4332-14
- Compression — ASTM D642-15
- Vibration — ASTM D4728-06(R2012), ASTM D999-08(2015)
- Drop — ASTM D5276-98(2009)
- Concentrated Impact — ASTM D6344-04(2009)
- Altitude — ASTM D6653/D6653M-13

Initial shelf life has been set based on available stability data as follows:

- Sonata® Radiofrequency Ablation Handpiece 1 year
- Sonata® RFA Handpiece Cable 1 year
- Sonata® Dispersive Electrode 3 years
- Sonata® Intrauterine Ultrasound Probe, Sterile 1 year

Biocompatibility

The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards as listed in Table 3. This biocompatibility evaluation established the biological safety for all of the changed patient contacting Sonata® System 2.1 devices.

Software

The three software items that comprise the software needed for the Sonata® System 2.1 have been developed, verified and validated to be safe and effective for its intended use. The software, in combination with its associated hardware of the SMART Tablet and the RF Generator, has been evaluated for safety, usability, communication between components, real time feedback to the user via the device's sensors, software/hardware interfaces and control of RF energy for ablation. Documentation consistent with a Major Level of Concern per the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005 was provided.

Electrical Safety and Electromagnetic Compatibility

The Sonata® System 2.1 complies with all the medical electrical safety and electromagnetic compatibility requirements of IEC 60601-1 3rd edition standards including ANSI/AAMI/ ES60601-1:2005/(R)2012 And A1:2012, C1:2009 / (R)2012 And A2:2010/(R)2012, the collateral standards for EMC IEC 60601-1-2 Ed 4:2014-02 and for alarms ANSI AAMI IEC 60601-1-8:2006 and A1:2012, particular standards of IEC 60601-2-2 Ed 6.0 2017-03 for high frequency surgical equipment and IEC 60601-2-37 Ed 2.1 2015 for Ultrasound equipment, IEC 62304 Ed 1.1 2015-06 for medical device software, and IEC 60601-1-6 Ed 3.1 2013-10 and IEC 62366-1:2015 for application of usability engineering to medical devices.

Human Factors

The Sonata® System 2.1 complies with usability requirements of IEC 60601-1-6 Ed 3.1 2013 and IEC 62366-1:2015. Summative human factors validation has been completed for treatment tasks as described in Table 4 to validate the acceptably of the updated RFA Handpiece with joystick (SMART Control), Confirm Button, modified position sensors and associated GGS changes.

Clinical Data

No additional clinical study data was needed to validate the Sonata® System 2.1.

Conclusion

The Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1 has the same intended use as the predicate device. The Sonata® System 2.1 combines radiofrequency ablation with intrauterine sonography in the same way as the predicate device, Sonata® System (K173703), and the technological differences do not raise different questions of safety and effectiveness. Performance data, including summative human factors validation data, demonstrate that the Sonata® System 2.1 is as safe and effective as the predicate device for diagnostic ultrasound imaging and ablation of uterine fibroids. Thus, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1 is substantially equivalent to its predicate device for its proposed indications.