August 15, 2018

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

Re: K173703
Trade/Device Name: Sonata® Sonography-Guided Transcervical Fibroid Ablation System
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar Endoscopic Coagulator-Cutter and Accessories
Regulatory Class: II
Product Code: KNF, ITX, IYO
Dated: July 14, 2018
Received: July 16, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K173703

Device Name
Sonata® Sonography-Guided Transcervical Fibroid Ablation System

Indications for Use *(Describe)*
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.

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: August 8, 2018

Device Information

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

Predicate Devices

The predicate devices are listed in Table 1. The primary predicate device is the Acessa System, and secondary predicates are the earlier Gynesonics EC6 intrauterine ultrasound transducer as used with the Terason t3000 Ultrasound System, and the Terason t3200 Ultrasound System.

None of the predicates have been subject to design-related recalls.

Table 1 Table of Predicates

510(k)	Product	510(k) Holder	Clearance Date
K121858	Acessa System	Acessa Health	Nov. 5, 2012
K061153	Gynesonics EC6 transducer with Terason™ t3000 Ultrasound System	Gynesonics	Oct. 27, 2006
K110020	Terason™ t3200 Ultrasound System	Teratech Corporation	Jan. 20, 2011

Device Description:

The Sonata System 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 (Figure 1), software, and various single-use and reusable instruments. Sonata System devices and accessories are summarized in Table 2.

Figure 1 Sonata System

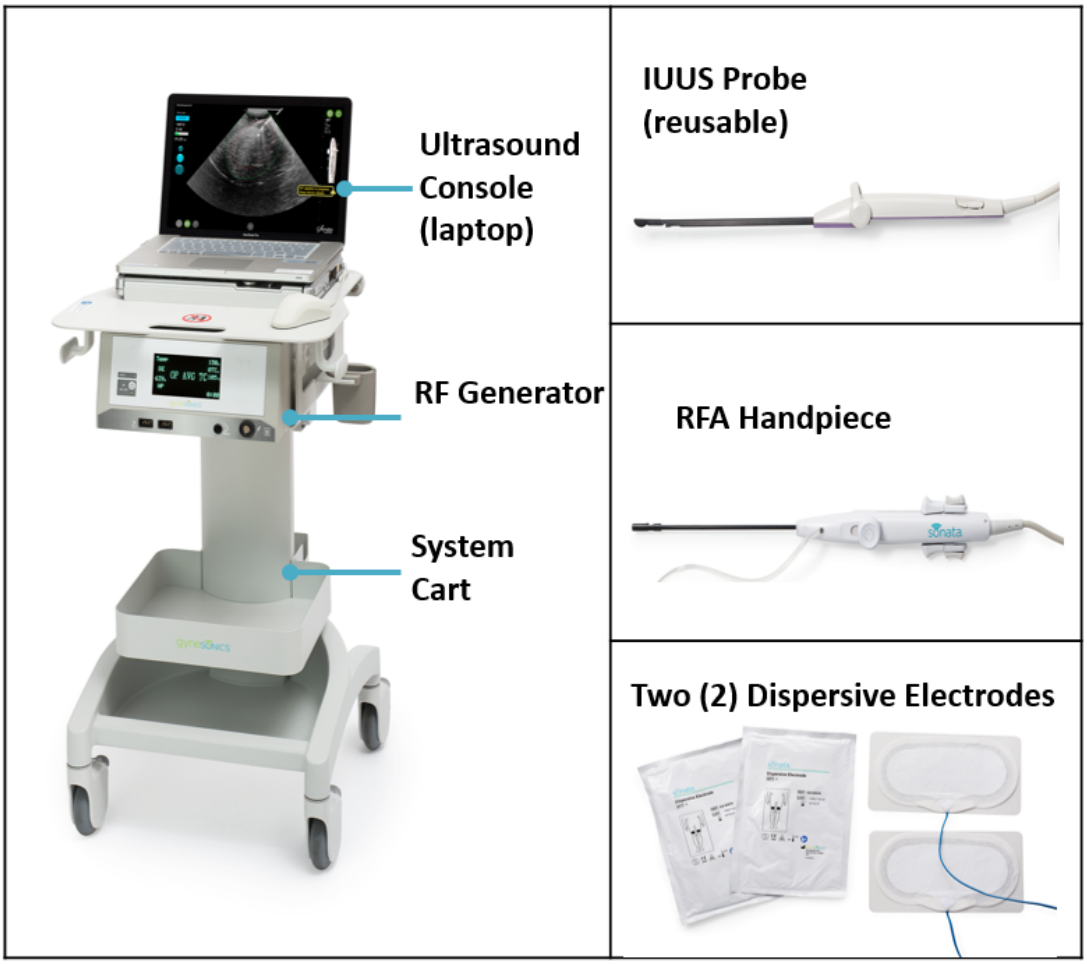
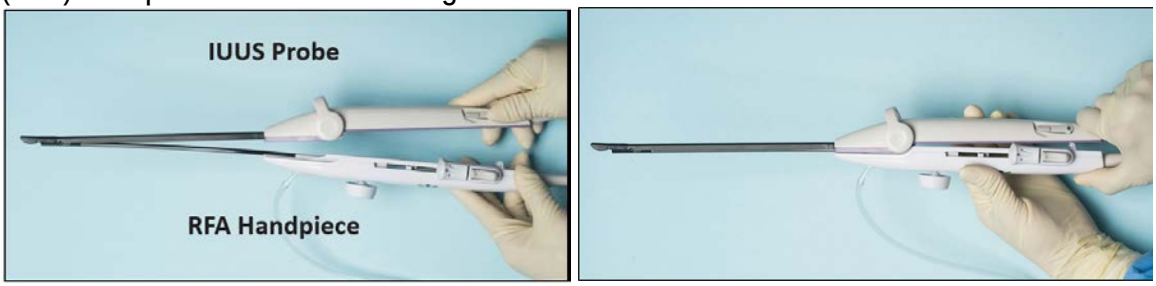


Table 2 Sonata System Devices and Accessories

Catalog Number	Product Description
Durable Equipment	
SONATA-110	Sonata Sonography-Guided Transcervical Fibroid Ablation System, consisting of:
RFG-110	Sonata Radiofrequency Generator
USCON-2100	Sonata Ultrasound Console
ACCY-001	Sonata System Cart
ACCY-003:	Sonata Component Kit; *contains manuals, footswitch, mouse, line cord, and cables*
Reusable Devices	
IUSP-001	Sonata Intrauterine Ultrasound (IUUS) Probe (Non-Sterile)
IUSP-001S	Sonata Intrauterine Ultrasound (IUUS) Probe (Sterile)
Procedure Pack with Single-Use Devices	
CSKIT-001	Sonata Case Kit; *contains:*
RFA-001	Sonata Radiofrequency Ablation Handpiece quantity 1, sterile
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
PE-001	Potential Equalization Kit
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 Ultrasound Console 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.

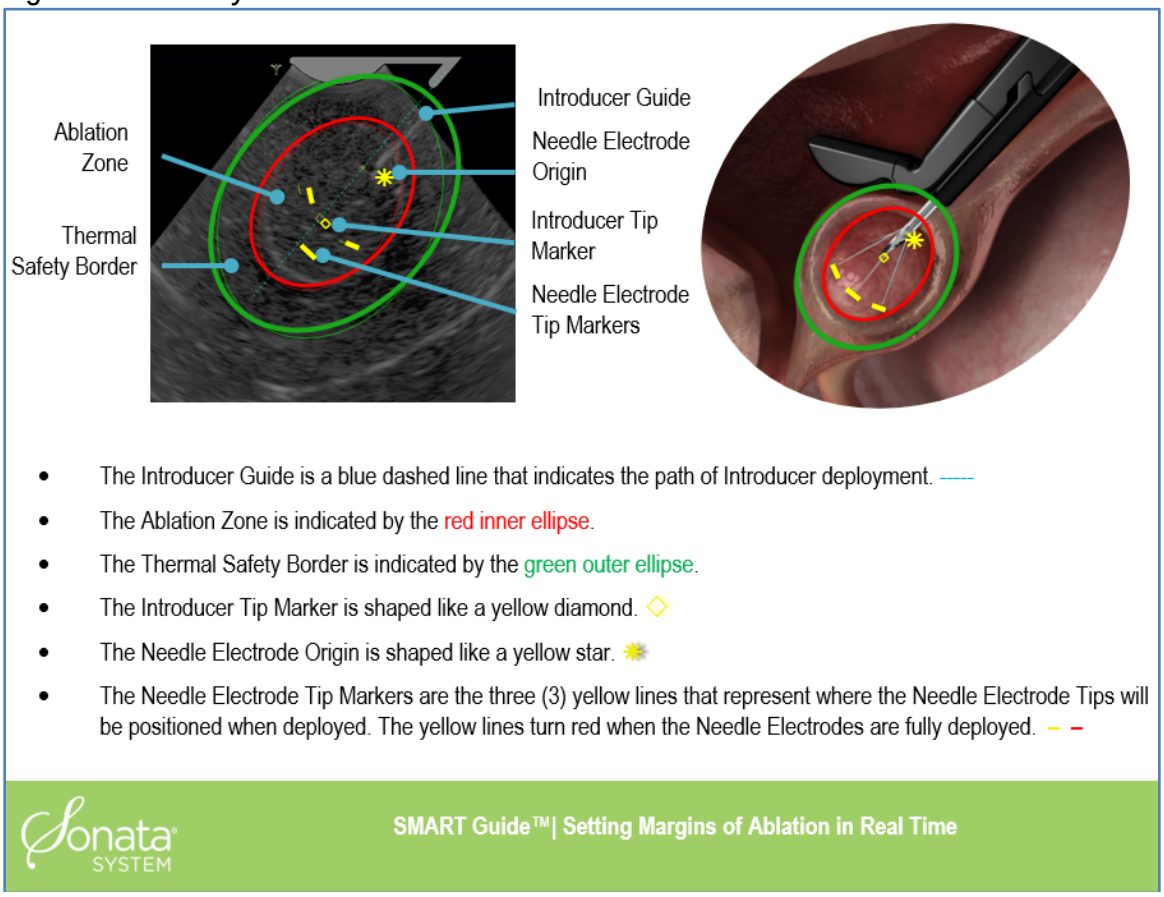
Figure 2 Intrauterine Ultrasound (IUUS) Probe connected to the Radiofrequency Ablation (RFA) Handpiece functions as a single Treatment Device



The Sonata System 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 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 Devices

The Sonata System combines radiofrequency ablation with intrauterine sonography. Because the Sonata System combines two functions into a single device, one predicate is used for the RF ablation function and two secondary predicates are used for the ultrasound visualization function.

Table 3 contains the discussion of similarities and differences between the subject device system and the predicate devices. 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

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Intended Use/Indications for Use					
Intended Use	Ablation of uterine fibroids with diagnostic ultrasound imaging.	Ablation of soft tissue including uterine fibroids with diagnostic ultrasound imaging.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Same. The Sonata System has the same intended use as one of Acessa's intended uses. The Sonata System's Ultrasound Console used with the Sonata Intrauterine Ultrasound Probe has the same intended use as one of the intended uses the Terason t3000 Ultrasound System used with the Gynesonics EC6 intrauterine ultrasound transducer, and of the Terason t3200 Ultrasound System.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
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.	Indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.	Indications for use include intrauterine and laparoscopic scanning and ultrasound guidance for placement of needles.	Indications for use include transvaginal and laparoscopic scanning, and ultrasound guidance for placement of needles.	Same. Sonata and Acessa are both intended for the ultrasound-guided RF ablation of uterine fibroids. Indications for Terason t3000 / EC6 and t3200 both include ultrasound guidance for placement of needles as ultrasound is used in the Sonata system and the EC6 predicate includes intrauterine scanning.
Regulation Number	§884.4160 Unipolar endoscopic coagulator-cutter and accessories	§884.4160 Unipolar endoscopic coagulator-cutter and accessories	§892.1570 Diagnostic ultrasonic transducer	§892.1550 Ultrasonic pulsed doppler imaging system	Same: Sonata and Acessa are same. The secondary predicates fall within ultrasound regulations.
Product Code	KNF Coagulator-Cutter, Endoscopic, Unipolar (And Accessories) ITX Transducer, Ultrasonic, Diagnostic IYO Ultrasonic pulsed echo imaging system	HFG Coagulator, Laparoscopic, Unipolar (And Accessories)	ITX Transducer, Ultrasonic, Diagnostic	ITX Transducer, Ultrasonic, Diagnostic IYN Ultrasonic pulsed doppler imaging system IYO Ultrasonic pulsed echo imaging system	Different. Sonata and Acessa have different product codes because of the different access route. The secondary predicates falls within ultrasound product codes.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
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.	Not applicable	Not applicable	Same. Sonata and Acessa have the same principal mode of operation.
	B Mode ultrasound imaging	Not applicable	B, M, PWD, color doppler, combination modes, harmonic ultrasound imaging	B, M, PWD, color doppler, combination modes, harmonic ultrasound imaging	Similar. The Sonata System imaging mode falls within the imaging modes of the ultrasound predicates.
Primary user interface	Graphical user interface	Graphical user interface	Graphical user interface	Graphical user interface	Same. The user interface for the Sonata System incorporates RF ablation and ultrasound imaging functionality within the ultrasound console. This difference does not raise different questions of safety and effectiveness.
Treatment Planning	Integrated SMART Guide in software	Operator must make manual measurements, use look up tables and determine multiple parameters for RF Generator manually	Not Applicable	Not Applicable	Similar. Sonata's software was evaluated for performance and usability. This difference does not raise different questions of safety and effectiveness.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
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.	Provides visualization for control (placement of needles).	Provides visualization for control (placement of needles).	Same Same as Acessa. In the case of Acessa, visualization for control is provided by a separate ultrasound system. In the case of Sonata, visualization is provided by the integrated ultrasound system. The Sonata ultrasound system and the secondary predicates t3000/EC6 and t3200 systems all provide visualization for placement of needles. This difference does not raise different questions of safety and effectiveness.
Treatment Guidance	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.	Must be used under ultrasound guidance provided by a separate ultrasound system.	Indicated for intrauterine imaging and guidance for placement of needles.	Indicated for transvaginal and laparoscopic scanning, and ultrasound guidance for placement of needles.	Same. Both the Sonata and Acessa systems utilize sonography for treatment guidance. Sonata has an integrated ultrasound system with IUUS Probe integrated directly into system whereas Acessa requires a separate ultrasound system and transducer. The Sonata System intrauterine imaging provides the same functionality as is indicated for the secondary predicates.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Route of Access	Transcervical	Laparoscopic	Transcervical	Transvaginal, intra-operative, laparoscopic	Different. Sonata and Acessa have different routes of access, but the EC6 includes transcervical access therefore the use of transcervical access rather than laparoscopic and percutaneous access does not raise different questions of safety and effectiveness in an ultrasound-guided procedure.
System Components					
RF Generator	An RF Generator provides RF energy to the RFA Handpiece through the handpiece cable	RF Generator, provides RF energy to the Handpiece through the handpiece cable	Not Applicable	Not Applicable	Sonata and Acessa are the same.
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.	Reusable intrauterine ultrasound probe	Various transducers	Similar The Sonata Treatment Device is the combination of the Acessa RFA handpiece and the EC6 ultrasound transducer.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Dispersive Electrodes	Dispersive Electrodes, quantity 2, with cables; provides return path for the RF energy delivered by the Handpiece	Dispersive Electrodes ("pads"), quantity 2, and cables; provides return path for the RF energy delivered by the Handpiece	Not Applicable	Not Applicable	Sonata and Acessa are the same.
Ultrasound Console	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)	Not Applicable	Incorporates the Terason t3000 Ultrasound System. The t3000 is a laptop-based system with 15" LCD display, lithium-ion battery (integrated into the laptop). Uses a medical-grade power supply. Data transferred internally from the ultrasound engine to the laptop computer over a FireWire (aka IEEE 1394)	The t3200 is a laptop-based system with 15" LCD display, lithium-ion battery (integrated into the laptop). Uses a medical-grade power supply. Data transferred internally from the ultrasound engine to the laptop computer over a FireWire (aka IEEE 1394).	Similar. The Terason t3200 (K110020) was determined to be substantially equivalent to its predicate Terason Echo / t3000 (K080234). Addition of the Sonata software to the ultrasound system optimizes the user interface for ease of use of the Sonata System. Some functionality unnecessary for diagnostic intrauterine imaging for ablation of uterine fibroids (e.g. M-mode) is removed to simplify the user interface, but it does not modify images or measurements in any way.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Ultrasound Transducer	Gynesonics Sonata Intrauterine Ultrasound (IUUS) Probe	Not applicable	Gynesonics EC6	Various	Similar. The Sonata IUUS Probe is designed with a handle that physically connects to the handle of the active electrode handpiece. The EC6 intrauterine ultrasound probe is integrated with the active electrode handpiece by inserting it through a lumen on the handpiece handle. Acoustic array design differences optimize device performance for use in the Sonata procedure. The difference does not raise any different questions of safety or effectiveness.
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 Generator.	Power cord - A medical grade power cord that provides AC power to the ultrasound system.	Power cord - A medical grade power cord that provides AC power to the ultrasound system.	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.	Not applicable	Not applicable	Sonata and Acessa are the same

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Optical Mouse	Optical Mouse	-----	Optical mouse	Optical mouse	Sonata and Terason are the same. A mouse is not part of the Acessa system. This difference does not raise different questions of safety and effectiveness.
System Cart	Cart	Acessa is used on a cart; the cart is not included in the Acessa System.	-----	-----	Similar. Sonata and Acessa are both installed on a cart for ease of use. Inclusion of the cart in the Sonata System does not raise different questions of safety or effectiveness. The Sonata System Cart meets applicable safety standards.
Materials					
Materials – Patient Contact – IUUS Probe	Glass fiber filled polyetherimide, glass reinforced vinyl ester, fluorocarbon rubber, UV adhesive, transparent film, epoxy filler.	Not applicable	Pebax 3533 Pebax 7033/Tecothane 2095	Not applicable	Different. Similar types of patient contact materials are used with the issues of safety and effectiveness resolved by demonstrating patient contact materials for the Sonata System to be biocompatible with respect to its intended use.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
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)	Not applicable	Not applicable	Similar. Biocompatibility of the active electrode materials has been demonstrated for both Sonata and Acessa.
Patient Contact Materials - dispersive electrode	Acrylate-polymer based hydrogel, polyester fabric with poly film and medical grade acrylic adhesive	Hydrogel	Not applicable	Not applicable	Similar. The Sonata Dispersive Electrode and the Acessa Pad utilize similar patient contact materials. For both the Sonata device and the predicate, patient contact materials are demonstrated to be biocompatible with respect to their intended use.
Biocompatibility	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 •	Is biocompatible with intended use in compliance with • ISO 10993-1 • ISO 10993-5 • ISO 10993-10	Is biocompatible with intended use in compliance with • ISO 10993-1:2003 • ISO 10993-5:1999 • ISO 10993-10:2002	Is biocompatible with intended use in compliance with • ISO 10993-5 • ISO 10993-10	Same Additional compliance demonstrated related to systemic toxicity, biocompatibility test sample preparation, and EO residuals after IUUS Probe reprocessing by ethylene oxide sterilization.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
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 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	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-2-2	EN/IEC 60601-1 EN/IEC 60601-2-37	IEC 60601-1 Ed 3 (2005) IEC 60601-1-6 Ed 2 (2006) IEC 60601-1-2 Ed 2:2001-09 IEC 60601-2-37 Ed 2 (2007) IEC 62366 Ed 1 (2007)	Sonata is to the same as one or more of the predicates. Sonata has 60601-1-6 applied for usability.
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.	• Shelf-life / Service life • Full system verification to specifications, standards, and guidance documents.	Information not available	Similar for three devices. Information is not available for the t3200 secondary predicate; however, the t3200 in K110020 has been incorporated into the Sonata System and therefore tested as a system.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	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	• Ablation output • RF Generator safety features • Handpiece retention forces • Ultrasound visibility of the handpiece • Dispersive Electrode (Pad) 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	Not Applicable	Not Applicable	Similar between Sonata and Acessa.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
(continued)	• 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.	• Successfully demonstrated through animal 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.			

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Acoustic Output Measurement Standard	NEMA UD 2-2004 (R2009) IEC 60601-2-37 Ed 2.0 2007	Not Applicable	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-1998 NEMA UD 3-2004	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	Not Applicable	• I_{SPTA} ≤ limit of 720 mW/cm^2 Value: 10 mW/cm^2 • MI ≤ limit of 1.9 Value: 0.4	• I_{SPTA} ≤ limit of 720 mW/cm^2 • MI ≤ limit of 1.9	Similar. The global maximum outputs are similar because both fall within the limits specified for Track 3 per FDA Guidance. The Sonata IUUS Probe operates with the Sonata System only in B Mode; therefore comparison is made only to global maximum outputs as measured in B Mode.

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
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 and reprocessing tasks.	-----	-----	IEC 60601-1-6 Ed 2 (2006) IEC 62366 Ed 1 (2007)	Different. Treatment planning functionality improves usability. Sponsor has applied latest FDA guidance and standards to design for and validate usability.
Performance testing: Clinical Results					
Clinical Trial to demonstrate safety and effectiveness.	IDE G140114 NCT02228174 n = 147 22 centers with treated patients Single-arm cohort study with each subject serving as her own control.	IDE G080163 NCT00874029 n = 137 11 centers Single-arm cohort study with each subject serving as her own control.	Not Applicable	Not Applicable	Equivalent

Characteristics	Sonata System (this submission)	Acessa System K121858 *(Primary)*	Terason t3000 / EC6 (K061153) *(Secondary)*	Terason t3200 (K110020) *(Secondary)*	Comparison Discussion
Co-primary efficacy endpoint of Reduction in Menstrual Blood Loss at 12 months. Success criterion: lower confidence limit (LCL) ≥ 45%	64.8% (95% CI 56.3% - 72.6%) Success criterion was met.	40.2% (95% CI 31.6% - 48.7%) Success criterion was not met.	Not Applicable	Not Applicable	Similar. Co-primary efficacy endpoint of Reduction in Menstrual Blood Loss and associated success criteria is the same for both Sonata and Acessa.
Co-primary efficacy endpoint of Surgical reintervention. Success criterion: LCL of the percentage of subject success ≥ 75%.	12-month reintervention: <0.7% (1 in 143) Success criterion was met.	12-month reintervention results have not been found in publicly available documents. Reintervention within 24 months: < 6% (6/107)	Not Applicable	Not Applicable	Similar. Co-primary efficacy endpoint of Surgical reintervention and associated success criteria is the same for both Sonata and Acessa.
Device-related Adverse Events	None	< 4%	Not Applicable	Not Applicable	Similar.

Performance Testing

The Sonata System 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 and clinical studies. 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.

Table 4 Sonata System Performance Testing - Bench

Aspect	Item / Model Number	Test	Test Methodology	Results
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
		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.
		Confirmatory Ablation Dimensions	Following setting of AZ and TSB, additional *ex vivo* ablation dimensions were measured with a non-perfused bovine tissue model in confirmatory study.	When tested with the Sonata System as submitted, dimensions of ablations produced in an *ex vivo* non-perfused bovine tissue model are consistent with the established AZ and TSB.
		Effect of Parameter Variations on Ablation Dimensions -		
		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.
		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.
		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.
		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.

Aspect	Item / Model Number	Test	Test Methodology	Results
Ultrasound Performance	Sonata System	Determination of Ultrasound Parameters	Small part phantom model to measure resolution, geometric accuracy, and image penetration. Beam profile & slice thickness phantom model to 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.
		Acoustic Output	Type testing of acoustic measurements according to IEC 60601-2-37 and FDA guidance.	MI = 1.7 which is under regulatory limit of 1.9. I_{SPTA} = 289 mW/cm^2 which is under regulatory limit of 720 mW/cm^2. Acoustic Output table completed per FDA guidance based on measurements made.
		Ultrasound Clinical Measurement Accuracy	Software unit testing on every software build of accuracy of linear measurements using a small parts ultrasound phantom.	Sonata System meets stated product specification for ultrasound clinical measurement accuracy.
Design Verification Testing - Individual Device	System Cart ACCY-001	Verification to Specifications	Type testing of System Cart for design requirements not covered in system testing per IEC 60601-1	Sonata System Cart meets stated its product specifications.
	RF Generator RFG-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.
	Ultrasound Console USCON-2100	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 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.
	IUUS Probe IUSP-001	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.
	IUUS Probe IUSP-001S	Verification to Specifications	Verification that the sterile IUUS Probe meets requirements for functionality after sterilization is addressed in the Sterilization/Shelf Life/Cleaning section below.	Refer to the Sterilization/Shelf Life/Cleaning section below.
	Sterile Shipper Kit SHPR-001	Verification to Specifications	Verification of physical requirements of shipper by inspection.	Sterile Shipper Kit meets its physical requirements.

Aspect	Item / Model Number	Test	Test Methodology	Results
Design Verification Testing - Individual Device (continued)	RFA Handpiece RFA-001	Verification to Specifications	Following Gamma 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.
	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.
		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.
	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.
	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.
	Potential Equalization Kit PE-001	Verification to Specifications	Verification of design requirements of Potential Equalization Kit by inspection and measurements.	Sonata Potential Equalization Kit meets its design requirements.

Aspect	Item / Model Number	Test	Test Methodology	Results
Design Verification Testing - Integrated System	Sonata System	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 meets its system level design requirements.
		Operating Conditions		
		Temperature / Relative Humidity	Type testing of system following environmental storage conditions, functional testing of system at range of operating temperature & relative humidity conditions.	Sonata System meets all acceptance criteria across range of specified system operating conditions.
		Altitude / Temperature	Functional type testing of system at range of temperatures and altitude limit.	Sonata System meets all acceptance criteria at maximum specified altitude across specified temperature range.
		Human Factors (HF) Evaluation		
		Human Factors – Treatment	15 Gynecologists and 15 support staff representative of typical users involved with performing RFA for fibroids participated in a HF study following manufacturer's provided training and training decay period. Participant pairs conducted one un-aided simulated ablation.	HF summative testing for treatment with the Sonata System 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.
		Human Factors – Reprocessing	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 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.

Sterilization/Shelf Life/Cleaning

The sterilization methods for the Sonata System device components provided sterile – the Radiofrequency Ablation (RFA) Handpiece 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
- Validation of Sterilization by Radiation ISO 11137-1:2006/A1:2013
- Establishing Radiation Dose ISO 11137-2:2013
- Validation of Sterilization by EO ISO 11135:2014
- Ethylene Oxide Sterilization Residuals ISO 10993-7:2008 with Technical Corrigendum 1

Recommended cleaning and sterilization methods described in applicable Instructions for Use for the reusable Sonata System 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 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 device components provided not sterile and without patient contact have been validated for distribution and transit stress. Validation has been performed according to:

- Selection of SAL ANSI/AAMI ST67:2011
- Validation of Sterilization by EO ISO 11135:2014
- Ethylene Oxide Sterilization Residuals ISO 10993-7:2008
- In Vitro Cytotoxicity ISO 10993-5:2009
- Allowable limits, leachable substances ISO 10993-17:2002(R2012)
- 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 and will be extended as appropriate when further shelf life test results become available.

- Sonata® Radiofrequency Ablation Handpiece 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 patient contacting Sonata System devices.

Software

The three software items that comprise the software needed for the Sonata System 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 Ultrasound Console 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 complies with all the medical electrical safety and electromagnetic compatibility requirements of IEC 60601-1 3rd edition standards including ANSI/AAMI/ ES60601:2005/(R)2012 And A1:2012, C1:2009 / (R)2012 And A2:2010/(R)2012, the collateral standards for EMC IEC 60601-1-2 Ed 3:2007-03 and for alarms IEC 60601-1-8 Ed 2.1 2012, and particular standards of IEC 60601-2-2:2009 for high frequency surgical equipment and IEC 60601-2-37 Ed 2.0 2007 for Ultrasound equipment.

Human Factors

The Sonata System complies with usability requirements of IEC 60601-1-6 Ed 3.1 2013 and IEC 62366-1:2015. Human factors validation has been completed for both treatment and reprocessing tasks as described in Table 4.

Clinical Data

SONATA Pivotal IDE Clinical Trial

The SONATA Pivotal IDE trial was a prospective, longitudinal, multicenter, single-arm cohort study to establish the safety and effectiveness of the Sonata System in the treatment of symptomatic uterine fibroids. The trial enrolled premenopausal women with symptomatic fibroids including heavy menstrual bleeding in the United States and Mexico to assess the performance of the Sonata System in the treatment of symptomatic uterine fibroids. SONATA was approved to enroll and treat 147 subjects at 27 investigational sites under IDE G140114 with ClinicalTrial.gov identifier NCT02228174. The safety objective of the study was addressed by the reporting of all adverse events (AEs). The efficacy objective of the study was addressed by two co-primary endpoints of Reduction in Menstrual Blood Loss (MBL) and Rate of No Surgical Re-intervention for heavy menstrual bleeding (HMB) due to treatment failure.

The co-primary efficacy endpoints, Reduction in MBL and Rate of No Surgical Re-intervention, are reached at 12 months post-procedure. Secondary endpoints of adverse events, quality of life and subject satisfaction questionnaires, and reduction in fibroid volumes were assessed following the procedure and at 12 months. Procedural parameters were also collected on the day of the procedure. Long term data collection continues for 3 years post-procedure for select measurements.

The safety objective was met as there was no occurrence of serious adverse device effect (SADE) or adverse device effect (ADE) and no unanticipated adverse device effect (UADE) in the study. A total of two procedure related serious adverse events (SAEs) occurred in two subjects. One involved a deep venous lower extremity thrombus diagnosed 15 days post-procedure, managed as an outpatient without sequelae. The other event involved a subject who presented with a chief complaint of leukorrhea, pelvic pain and unconfirmed low-grade fever at 28 days post-procedure and was managed with overnight admission and broad-spectrum antibiotics.

Co-Primary Endpoints

As shown in Table 5 the co-primary efficacy endpoint of Reduction in MBL at 12 months exceeded the success criteria of lower-confidence limit (LCL) $\geq$ 45% with 64.8% of subjects having a reduction of at least 50% in the 12-Month Visit PBAC and a final 12-Month Visit Pictorial Blood Loss Assessment Chart (PBAC) score of less than 250 (LCL was 56.3%). There was a reduction in the 12-Month Visit PBAC score in 95.1% of subjects.

Table 5: SONATA Pivotal IDE Clinical Study Co-Primary Endpoints at 12 Months

Co-Primary Endpoints	Result	Success Criteria	Outcome
≥ 50% Reduction in PBAC and PBAC <250 at 12-Month Visit		Lower bound of 2- sided 95% CI > 45%	Met Endpoint Success Criteria
Total Number of Subjects in the Population[1]	142		
Success (%)	91 (64.8%)		
95% CI (LCL, UCL)	56.3%, 72.6%		
Rate of No Surgical Re-intervention through 12 Months		Lower bound of 2-sided 95% CI > 75%	Met Endpoint Success Criteria
Total Number of Subjects in the Population[2]	143		
Rate %	99.3%		
95% CI (LCL, UCL)	95.1%, 99.9%		

[1] Five (5) subjects were excluded due to interfering medical condition (4) and re-intervention (1) per protocol.
[2] Four (4) subjects were excluded due to interfering medical condition per protocol.

Secondary Endpoints

Additional analyses of secondary endpoints lead to the following observations:

- 96% of subjects reported symptom improvement at 12 months
- 97% of subjects were satisfied at 12 months
- 97% of subjects were likely to recommend Sonata to friends at 12 months
- 99% of subjects were free from surgical reintervention at 12 months
- 95% of subjects had a reduction in bleeding by 12 months
- 98% of subjects found the procedure tolerable at 12 months
- 4.7% of subjects reported the procedure as minimally tolerable or intolerable
- At least 50% of subjects returned to normal activity the next day
- 74% of subjects had a short length of stay ≤ 3 hours

The treatment of symptomatic uterine fibroids with the Sonata System has been shown to be safe and effective as the study met the pre-specified hypotheses of effectively reducing menstrual bleeding with a low surgical re-intervention rate at 12 months with favorable safety outcomes.

FAST-EU Clinical Trial

The FAST-EU was a multicenter, prospective, longitudinal, single-arm trial that enrolled and treated 50 subjects with symptomatic uterine fibroids using the VizAblate System (now called Sonata) from 2011 to 2013. The trial met its primary endpoint of percentage change in perfused fibroid volume at 3 months (mean reduction of 68.1% ± 28.6%) as well as demonstrated a significant reduction in menstrual bleeding and improvements in overall clinical symptoms and quality of life. Furthermore, symptom relief and fibroid volume reduction were sustained through 12 months[1].

Conclusion

The Sonata Sonography-Guided Transcervical Fibroid Ablation System has the same intended use as the predicate devices. The Sonata System combines technological characteristics of the predicate devices into one device, and the technological differences do not raise different questions of safety and effectiveness. Performance data, including clinical data, demonstrate that the Sonata System is as safe and effective as the predicate devices for diagnostic ultrasound imaging and ablation of uterine fibroids. Thus, the Sonata Sonography-Guided Transcervical Fibroid Ablation System is substantially equivalent to its predicate devices for its proposed indications.

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[1] Brölmann H, Bongers M, Garza-Leal J, Gupta J, Veersema S, Quartero R, et al. The FAST-EU trial: 12-month clinical outcomes of women after intrauterine sonography-guided transcervical radiofrequency ablation of uterine fibroids. *Gynecol Surg*. 2016;13(1):27-35.