March 5, 2019

Seno Medical Instruments, Inc.
% Ms. Ann Waterhouse
VP Regulatory Affairs/Quality Assurance
8023 Vantage Drive, Suite 1000
SAN ANTONIO TX 78240

Re: K182628
Trade/Device Name: Imagio® Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 7, 2019
Received: February 11, 2019

Dear Ms. Waterhouse:

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,

for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182628

Device Name
Imagio® Ultrasound Imaging System

Indications for Use *(Describe)*
The Imagio Ultrasound Imaging System is intended for the following applications:
Abdominal, Small Parts, Musculoskeletal conventional, and Musculoskeletal superficial.

The system also provides the ability to measure anatomical structures {abdominal, small organ, and musculo-skeletal} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The ultrasound platform is similar to the predicate devices in terms of operation. A transducer is applied to the patient and the system generates ultrasound waves then transmit the wave into the human body. The system then receives echoes back from the human body, processing them to yield an image on a display.

The indications for use included in the Imagio Ultrasound Imaging System comprise a subset of indications supported by the predicate device. Only one of the transducers (L14-5/38) supported by the predicate device are supported on the Imagio Ultrasound Imaging System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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System: Imagio® Breast Imaging System
Transducer: L14-5/38

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic	No	No	No	No	No	No	No
Fetal Imaging & Other	Fetal	No	No	No	No	No	No	No
	Abdominal	Yes	No	Yes	No	Yes	Yes	No
	Intra-operative (Specify)	No	No	No	No	No	No	No
	Intra-operative (Neuro)	No	No	No	No	No	No	No
	Laparoscopic	No	No	No	No	No	No	No
	Pediatric	No	No	No	No	No	No	No
	Small Organ (Breast) Small Organ (Thyroid)	Yes	No	Yes	No	Yes	Yes	No
	Neonatal Cephalic	No	No	No	No	No	No	No
	Adult Cephalic	No	No	No	No	No	No	No
	Trans-rectal	No	No	No	No	No	No	No
	Trans-vaginal	No	No	No	No	No	No	No
	Trans-urethral	No	No	No	No	No	No	No
	Trans-esoph. (non-Card.)	No	No	No	No	No	No	No
	Musculo-skeletal (**Conventional**)	Yes	No	Yes	No	Yes	Yes	No
	Musculo-skeletal (**Superficial**)	Yes	No	Yes	No	Yes	Yes	No
	Intravascular	No	No	No	No	No	No	No
	Other (Specify)	No	No	No	No	No	No	No
Cardiac	Cardiac Adult	No	No	No	No	No	No	No
	Cardiac Pediatric	No	No	No	No	No	No	No
	Intravascular (Cardiac)	No	No	No	No	No	No	No
	Trans-esoph. (Cardiac)	No	No	No	No	No	No	No
	Intra-cardiac	No	No	No	No	No	No	No
	Other (Specify)	No	No	No	No	No	No	No
Peripheral Vessel	Peripheral vessel	No	No	No	No	No	No	No
	Other (Specify)	No	No	No	No	No	No	No

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Tissue Motion Doppler, and Color Velocity Imaging

5 510(k) Summary K182628

In accordance with 21 CFR 807.92 the following summary of information is provided:

Traditional 510(k): Imagio® Ultrasound Imaging System

510(k) Submitter:

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Date Prepared: 7 February 2019
Common Name: Ultrasound Imaging System
Proprietary/Trade Name: Imagio® Ultrasound Imaging System
Review Panel: Radiology

Classification Name:

Regulation Description	Device	CFR. Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	System, Imaging, Pulsed Doppler, Ultrasonic	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	System, Imaging, Pulsed Echo, Ultrasonic	892.1560	90-IYO
Diagnostic Ultrasound Transducer	Transducer, Ultrasonic, Diagnostic	892.1570	90-ITX

Classification: Class II

Predicate Name(s):

Predicate Name	510(K) Number
Sonix MDP Ultrasound Scanner	K080935

Clearance Request for: Imagio® Ultrasound Imaging System

5.1 Device Description

The Imagio Ultrasound Imaging System is a multi-purpose mobile, software controlled diagnostic ultrasound system with on-screen thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire echo data and display it in B-Mode, Pulsed (PW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic imaging on a Flat Panel Display. The user interface includes specialized controls, a minimized computer keyboard, and touch panel on an ergonomic console.

The systems provide measurement capabilities for anatomical structures that provide information used for clinical diagnostic purposes. The system has a PW audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities. The systems include a Digital Imaging and Communications (DICOM) module which enables storage.

The system is designed for use in linear scanning modes, and supports linear array probes.

The Imagio Ultrasound Imaging System is comprised of the following subsystems provided by Analogic Corporation, (previously Ultrasonix), and used in common with the predicate device:

- Modulo – ultrasound acquisition subsystem:
  - ultrasound transmit and receive electronics;
  - transducer interface – connection to transducer accessory;
  - computer – control, image formation, and image processing;
- control console;
- clinical display;
- L14-5/38 transducer;
- ultrasound imaging software;

The above subsystems from the predicate device are incorporated in the Imagio Ultrasound Imaging System together with the following Seno Medical designed components:
Cart Mechanical Design

- frame;
- casters;
- wheel locking;
- adjustable height mounting arm for console and display;
- cart electrical;
  - electrical wiring and optical cables;
  - power distribution unit;
- enclosures;
- USB alpha-numeric keyboard assembly.

Note that the Analogic software has been modified to remove support for applications and transducers not needed by Seno Medical customers.

Frequency Range	2-15MHz
Transducer types	Linear array

System	Imagio System					
Probe	US/L-14-5 Probe					
Intended Use	Real-time conventional diagnostic ultrasound with color and pulsed wave Doppler for fluid flow analysis					
Indications as follows:						
Clinical Application	**Modes of Operation**					
Specific (Track 3)	B	M	PWD	CW	Color/Power Doppler*1 (CD/PD)	Combined*2
Small Organ: Breast	Yes	No	Yes	No	Yes	Yes
Small Organ: Thyroid	Yes	No	Yes	No	Yes	Yes
Abdominal	Yes	No	Yes	No	Yes	Yes
Muskuloskeletal (MSK)	Yes	No	Yes	No	Yes	Yes

*1. Power Doppler is also referred to as Amplitude Doppler (AD) or Directional Power Doppler (DPD); Color Doppler is also referred to as color flow mapping (CFM);

*2. B/PWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD

5.2 Intended Use

The Imagio Ultrasound Imaging System is intended for the following applications: Abdominal, Small Parts, Musculoskeletal conventional, and Musculoskeletal superficial.

The system also provides the ability to measure anatomical structures {abdominal, small organ, and musculo-skeletal} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The ultrasound platform is similar to the predicate devices in terms of operation. A transducer is applied to the patient and the system generates ultrasound waves then transmit the wave into the human body. The system then receives echoes back from the human body, processing them to yield an image on a display.

The indications for use included in the Imagio Ultrasound Imaging System comprise a subset of indications supported by the predicate device. Only one of the transducers (L14-5/38) supported by the predicate device are supported on the Imagio Ultrasound Imaging System.

Functional Use:

A clinician initiates an exam via the system user interface composed of the control console and display, by entering patient information, and selecting exam type. The clinician then connects the transducer to modulo ultrasound acquisition subsystem (if not previously connected), and selects the transducer. The user applies the transducer to the patient area of interest. The acquisition subsystem generates and applies high frequency pulsed waveforms to the transducer, which in-turn converts the electrical pulses into ultrasound acoustic pulses transmitted into the human body. The transducer then receives echoes back from the human body, and converts them into electrical signals applied to the acquisition subsystem ultrasound receivers. Each received signal is digitized and combined by the acquisition subsystem computer to generate ultrasound images. The images are presented to user on the clinical display. The clinician may adjust imaging parameters, perform measurements, annotate, and store images via the control console. All of the above mentioned subsystems, incorporated into Imagio are common to the predicate device.

This device does not include any imaging modes that were not present on the predicate device; all of the modes and ultrasound imaging feature were provided as part of the Analogic Corporation components common to the predicate device. This includes spatial compound imaging, sound velocity, and features such as auto gain.

While the Intended Use statement for the Imagio Ultrasound Imaging System is not identical to the predicate device (Removal of application and associated transducers), the difference does not alter the intended diagnostic use of the device nor does it affect the safety and effectiveness of the device relative to the predicate.

The ultrasound platform is similar to the predicate device in terms of operation. A transducer is applied to the patient and the system generates ultrasound waves. These waves echo back from the human body, and the system processes them to yield an image/display.

Please see Section 12, Comparison between the Imagio Ultrasound Imaging System and the listed predicate device(s).

5.3 Indications for Use

The Imagio Ultrasound Imaging System is intended for the following applications:

Abdominal, Small Parts, Musculoskeletal conventional, and Musculoskeletal superficial.

The system also provides the ability to measure anatomical structures {abdominal, small organ, and musculo-skeletal} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The ultrasound platform is similar to the predicate devices in terms of operation. A transducer is applied to the patient and the system generates ultrasound waves then transmit the wave into the human body. The system then receives echoes back from the human body, processing them to yield an image on a display.

The indications for use included in the Imagio Ultrasound Imaging System comprise a subset of indications supported by the predicate device. Only one of the transducers (L14-5/38) supported by the predicate device are supported on the Imagio Ultrasound Imaging System.

5.4 Comparison of Technological Characteristics with the Predicate Device

The technological characteristics are substantially similar to that of the predicate(s). The device operates identically to the predicate device(s) in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Flow Mapping Doppler, Power Doppler, Continuous Wave Doppler) are the same as the predicate devices identified. Transducer patient contact materials are biocompatible.

The beam forming architecture is exact to that of the predicate device(s). The receiving and processing hardware is identical in that it is a programmable system made of 2 building blocks, which can be reconfigured to operate the system in any referenced imaging mode.

The parameters used to adjust image quality are the same as that seen in the predicates. This includes the use of TGC gain sliders, depth control, base control and angling, among others.

The Imagio Ultrasound Imaging System is substantially equivalent to the predicate device(s) with regard to intended use/indications for use, and technological characteristics of the offered transducer.

5.5 Performance Data/Determination of Substantial Equivalence

The Imagio Ultrasound Imaging System has been evaluated for acoustic output, biocompatibility and cleaning and disinfection. The system has been found to conform with thermal, electrical, electromagnetic, and mechanical safety and has been found to conform to applicable medical device safety standards. Please see Table 1 below for a list of compliance standards.

Table 1: Imagio and US/L-14-5 Transducer Summary of Standards

Standard	Title
EN ISO 10993-1 :2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (ISO 10993-1 :2009)
EN ISO 10993-5 :2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5 :2009)
ISO 10993-10: 2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices (ISO 14971: 2007, Corrected version 2007-10-01)
ANSI/AAMI ES60601-1:2005/A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007)
EN IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
IEC 60601-2-37:2007 + A1:2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304:2006 + A1:2015	Medical device software - Software life cycle processes
EN IEC 62366:2010	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
UD2 NEMA Measurement: 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3
UD3 NEMA 3-2004:	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2

The devices acoustic output limits are:

I_{SPTA} (d)	720mW/cm^2
TIS/TIB/TIC	0.1 – 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0 – 700W/cm^2 (Range)

*The limits are the same as predicate Track 3 devices

5.6 Clinical Testing

Since the Imagio Ultrasound Imaging System utilizes the same technology and principles as the existing predicate device Sonix MDP Ultrasound Scanner (K080935), clinical studies were not required to support substantial equivalence.

5.7 Conclusion

The intended uses and other key features are consistent with traditional clinical practice, FDA guidance's, guidelines, and established methods of patient examinations. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing manufacturer surveillance. Diagnostic ultrasound and imaging has a long history of safe and effective performance.

As such, the data herein supports this device, the Imagio Ultrasound Imaging System and the recommended transducer, US/L-14-5, as substantially equivalent with respect to safety and effectiveness to the currently cleared predicate device(s).