FUJIFILM SonoSite Inc.
% Anoush Frankian
Senior Manager, Regulatory Affairs
21919 30th Drive SE
BOTHELL WA 98021

September 1, 2020

Re: K202160
Trade/Device Name: Sonosite PX Ultrasound System, Sonosite SII Ultrasound System, Sonosite iViz Ultrasound System, Sonosite X-Porte Ultrasound System, Sonosite Edge II Ultrasound System, Sonosite Maxx Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, OIJ, ITX, LLZ
Dated: August 3, 2020
Received: August 3, 2020

Dear Anoush Frankian:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

K202160

Device Name

Sonosite PX Ultrasound System

Indications for Use *(Describe)*

The Sonosite PX Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Abdominal
Adult cephalic
Cardiac Adult
Cardiac Pediatric
Fetal - OB/GYN
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Ophthalmic
Pediatric
Peripheral Vessel
Small Organ (breast, thyroid, testicles, prostate)
Transvaginal
Needle Guidance

This device is indicated for Prescription Use Only.

The Sonosite PX Ultrasound System is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients.

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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"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)*

K202160

Device Name

SonoSite SII Ultrasound System

Indications for Use *(Describe)*

The SonoSite SII Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Ophthalmic
Fetal - OB/GYN
Abdominal
Pediatric
Small Organ (breast, thyroid, testicle, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-rectal
Trans-vaginal
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Cardiac Adult
Cardiac Pediatric
Peripheral Vessel

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)

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*See PRA Statement below.*

510(k) Number *(if known)*

K202160

Device Name

SonoSite iViz Ultrasound System

Indications for Use *(Describe)*

The SonoSite iViz Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use in clinical care by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis. Specific clinical applications and exam types include:

Fetal - OB/GYN
Abdominal
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Peripheral vessel
Ophthalmic

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K202160

Device Name

SonoSite X-Porte Ultrasound System

Indications for Use *(Describe)*

The SonoSite X-Porte Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Ophthalmic
Fetal – OB/GYN
Abdominal
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-vaginal
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Trans-esophageal (card.)
Peripheral Vessel

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)

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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)*

K202160

Device Name

SonoSite Edge II Ultrasound System

Indications for Use *(Describe)*

The SonoSite Edge II Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Ophthalmic
Fetal - OB/GYN
Abdominal
Pediatric
Small Organ (breast, thyroid, testicle, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-rectal
Trans-vaginal
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Cardiac Adult
Cardiac Pediatric
Trans-esophageal (cardiac)
Peripheral Vessel

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)

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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)*

K202160

Device Name

Sonosite Maxx Ultrasound System

Indications for Use *(Describe)*

The SonoSite Maxx Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications include:
Ophthalmic, Fetal - OB/GYN, Abdominal, lntraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel.

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)

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## 510(k) SUMMARY - K202160

## FUJIFILM Sonosite Diagnostic Ultrasound Systems

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.

Date Prepared: July 30th, 2020

### I. Submitter


**Manufacturer Name And Address**

FUJIFILM Sonosite Inc
21919 30th Drive SE
Bothell, WA 98021-3904

**Contact Information:**

Anoush Frankian
Sr. Manager, Regulatory Affairs
anoush.frankian@fujifilm.com
(425) 951-6824
(425) 659-0186


### II. Device

**Common/Usual Name:**

Diagnostic Ultrasound System with Accessories

**Proprietary Name:**

Sonosite PX Ultrasound System
Sonosite SII Ultrasound System
Sonosite iViz Ultrasound System
Sonosite Edge II Ultrasound System
Sonosite X-Porte Ultrasound System
Sonosite Maxx Ultrasound System

**Device Classification and Product Code:**

| Name | CFR Number | Product Code |
|---|---|---|
| **Ultrasonic Pulsed Doppler Imaging System** | 892.1550 | IYN |
| **Ultrasonic Pulsed Echo Imaging System** | 892.1560 | IYO |

| Name | CFR Number | Product Code |
|---|---|---|
| **Ultrasonic Pulsed Echo Imaging System** | 892.1560 | OIJ |
| **Diagnostic Ultrasound Transducer** | 892.1570 | ITX |
| **Picture Archiving and Communications System** | 892.2050 | LLZ |

## III. Predicate Device:

Sonosite PX Ultrasound System (K200964)
Sonosite iViz Ultrasound System (K180704)
Sonosite Edge II Ultrasound System (K162045)
Sonosite X-Porte Ultrasound System (K171437)
Sonosite SII Ultrasound System (K183235)
Sonosite Maxx Ultrasound System (K130173)

## IV. Device Description

The Sonosite Diagnostic Ultrasound Systems are full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. They are intended to be used for general purpose ultrasound examination, cardiac imaging, fetal imaging and OB/GYN applications, vascular imaging and trans-vaginal and trans-rectal applications and fluid flow analysis among others. Some Sonosite Diagnostic Ultrasound Systems (Sonosite PX) also have needle guidance capabilities. They are intended to be used by qualified physicians and trained professionals in various patient care settings including hospitals, clinics, and point-of-care settings. Software modes/applications, scanning protocols, and pre-installed settings or functionality to create dedicated settings for imaging of specific anatomy are available with the subject Sonosite Diagnostic Ultrasound Systems and may vary among the different model configurations. The Sonosite Diagnostic Ultrasound Systems work on either battery or AC power. Some Sonosite Diagnostic Ultrasound Systems support Bluetooth and wireless connectivity for image transfer and over-the-air (OTA) software updates.

The diagnostic ultrasound systems are manufactured with hardware components which consist of:

1) a primary console (e.g., workstation, tablet with touchscreen) with built-in software components, features, and various clinical applications, and

2) a range of compatible ultrasound transducers.

A suite of compatible transducers are offered with the Sonosite Diagnostic Ultrasound Systems. These include linear array, curved array, phased array, intra-cavitary, static probes and trans-esophageal transducers. Linear array transducers (prefixed with the letter L) produce a rectangular field of view with uniform beam density throughout and are useful for imaging shallow structures and small parts. Curved array transducers (prefixed with the letter C) allow for a wider field of view but with decreased line density at depth and reduced lateral resolution. They are the ideal probe for lung ultrasound imaging. Phased array transducers (prefixed with the letter P) are small faced transducers allowing for imaging in small spaces. They are able to change the focus of

the ultrasound beam. It is the optimal transducer recommended for cardiac imaging. Trans-esophageal transducers (prefixed with the letters TE) are commonly used for evaluation of cardiac and aortic structures. Intra-cavitary transducers (prefixed with the letters IC) are used for trans-vaginal or trans-rectal ultrasounds.

Some models may have additional previously-cleared accessories, or components which are manufactured by other manufacturers.

## V. Indications for Use

| Device | Indication for Use |
|---|---|
| **Sonosite PX** | The Sonosite PX Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Abdominal<br>Adult cephalic<br>Cardiac Adult<br>Cardiac Pediatric<br>Fetal – OB/GYN<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Ophthalmic<br>Pediatric<br>Peripheral Vessel<br>Small Organ (breast, thyroid, testicles, prostate)<br>Transvaginal<br>Needle Guidance<br><br>This device is indicated for Prescription Use Only.<br><br>The Sonosite PX Ultrasound System is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients. |
| **Sonosite SII** | The SonoSite SII Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal - OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicle, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-rectal<br>Trans-vaginal<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Cardiac Adult<br>Cardiac Pediatric<br>Peripheral Vessel |

| Device | Indication for Use |
|---|---|
| | |
| **Sonosite iViz** | The SonoSite iViz Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use in clinical care by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis. Specific clinical applications and exam types include:<br><br>Fetal – OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicles, prostate)<br>Musculo-skel. (Convent.)<br>Musculo-skel. (Superfic.)<br>Cardiac Adult<br>Cardiac Pediatric<br>Peripheral vessel<br>Ophthalmic |
| **Sonosite X-Porte** | The SonoSite X-Porte Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal – OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicles, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-vaginal<br>Musculo-skel. (Convent.)<br>Musculo-skel. (Superfic.)<br>Cardiac Adult<br>Cardiac Pediatric<br>Trans-esophageal (card.)<br>Peripheral Vessel |
| **Sonosite Edge II** | The SonoSite Edge II Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal - OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicle, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-rectal<br>Trans-vaginal<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Cardiac Adult<br>Cardiac Pediatric |

| Device | Indication for Use |
|---|---|
| | Trans-esophageal (cardiac)<br>Peripheral Vessel |
| **Sonosite Maxx** | The SonoSite Maxx Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications include:<br>Ophthalmic, Fetal - OB/GYN, Abdominal, lntraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel. |

## VI. Comparison of Technological Characteristics with the Predicate Device

**Table 1: Technological Comparison of Subject Device (Sonosite PX Ultrasound System) and Predicate Device**

| Standard Feature | Sonosite PX Ultrasound System (Subject Device) | Sonosite PX Ultrasound System - K200964 (Predicate Device) | Comparison |
|---|---|---|---|
| **Indications for Use** | The Sonosite PX Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Abdominal<br>Adult Cephalic<br>Cardiac Adult<br>Cardiac Pediatric<br>Fetal – OB/GYN<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Ophthalmic<br>Pediatric<br>Peripheral vessel<br>Small Organ (breast, thyroid, testicles, prostate)<br>Transvaginal<br>Needle Guidance<br><br>This device is indicated for Prescription Use Only. | The Sonosite PX Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Abdominal<br>Adult Cephalic<br>Cardiac Adult<br>Cardiac Pediatric<br>Fetal – OB/GYN<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Ophthalmic<br>Pediatric<br>Peripheral vessel<br>Small Organ (breast, thyroid, testicles, prostate)<br>Transvaginal<br>Needle Guidance<br><br>This device is indicated for Prescription Use Only. | Identical |

| Standard Feature | Sonosite PX Ultrasound System (Subject Device) | Sonosite PX Ultrasound System - K200964 (Predicate Device) | Comparison |
|---|---|---|---|
| | The Sonosite PX Ultrasound System is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients. | The Sonosite PX Ultrasound System is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients. | |
| **Reusable?** | Yes | Yes | Identical |
| **Duration of Use** | Limited (<24 hours) | Limited (<24 hours) | Identical |
| **Scientific Technology** | Ultrasound Imaging | Ultrasound Imaging | Identical |
| **Operating Principle** | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | Identical |
| **Type of Previously Cleared Transducers** | Linear Array<br>Curved Array<br>Phased Array<br>Intracavitary | Linear Array<br>Curved Array<br>Phased Array<br>Intracavitary | Identical |
| **Acoustic Outputs Within Range?** | Yes | Yes | Identical |
| **Previously Cleared Imaging Modes?** | Yes | Yes | Identical |
| **Biocompatibility** | Per ISO 10993-1 | Per ISO 10993-1 | Identical |

**Table 2: Technological Comparison of Subject Device (Sonosite SII Ultrasound System) and Predicate Device**

| Standard Feature | Sonosite SII Ultrasound System (Subject Device) | Sonosite SII Ultrasound System - K183235 (Predicate Device) | Comparison |
|---|---|---|---|
| **Indications for Use** | The SonoSite SII Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal - OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicle, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-rectal<br>Trans-vaginal<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Cardiac Adult<br>Cardiac Pediatric<br>Peripheral Vessel | The SonoSite SII Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal - OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicle, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-rectal<br>Trans-vaginal<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Cardiac Adult<br>Cardiac Pediatric<br>Peripheral Vessel | Identical |
| **Reusable?** | Yes | Yes | Identical |
| **Duration of Use** | Limited (<24 hours) | Limited (<24 hours) | Identical |
| **Scientific Technology** | Ultrasound Imaging | Ultrasound Imaging | Identical |
| **Operating Principle** | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | Identical |

| Standard Feature | Sonosite SII Ultrasound System (Subject Device) | Sonosite SII Ultrasound System - K183235 (Predicate Device) | Comparison |
|---|---|---|---|
| **Type of Previously Cleared Transducers** | Linear Array<br>Curved Linear Array<br>Phased Array<br>Intracavitary | Linear Array<br>Curved Linear Array<br>Phased Array<br>Intracavitary | Identical |
| **Acoustic Outputs within Range?** | Yes | Yes | Identical |
| **Previously Cleared Imaging Modes?** | Yes | Yes | Identical |
| **Biocompatibility** | Per ISO 10993-1 | Per ISO 10993-1 | Identical |

**Table 3: Technological Comparison of Subject Device (Sonosite iViz Ultrasound System) and Predicate Device**

| Standard Feature | Sonosite iViZ Ultrasound System (Subject Device) | Sonosite iViz Ultrasound System - K180704 (Predicate Device) | Comparison |
|---|---|---|---|
| **Indications for Use** | The SonoSite iViz Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use in clinical care by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis. Specific clinical applications and exam types include:<br><br>Fetal – OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicles, prostate)<br>Musculo-skel. (Convent.)<br>Musculo-skel. (Superfic.)<br>Cardiac Adult<br>Cardiac Pediatric<br>Peripheral vessel<br>Ophthalmic | The SonoSite iViz Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use in clinical care by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis. Specific clinical applications and exam types include:<br><br>Fetal – OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicles, prostate)<br>Musculo-skel. (Convent.)<br>Musculo-skel. (Superfic.)<br>Cardiac Adult<br>Cardiac Pediatric<br>Peripheral vessel<br>Ophthalmic | Identical |
| **Reusable?** | Yes | Yes | Identical |
| **Duration of Use** | Limited (<24 hours) | Limited (<24 hours) | Identical |

| Standard Feature | Sonosite iViZ Ultrasound System (Subject Device) | Sonosite iViz Ultrasound System - K180704 (Predicate Device) | Comparison |
|---|---|---|---|
| **Scientific Technology** | Ultrasound Imaging | Ultrasound Imaging | Identical |
| **Operating Principle** | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | Identical |
| **Type of Previously Cleared Transducers** | Linear Array<br>Curved Array<br>Phased Array | Linear Array<br>Curved Array<br>Phased Array | Identical |
| **Acoustic Outputs Within Range?** | Yes | Yes | Identical |
| **Previously Cleared Imaging Modes?** | Yes | Yes | Identical |
| **Biocompatibility** | Per ISO 10993-1 | Per ISO 10993-1 | Identical |

**Table 4: Technological Comparison of Subject Device (Sonosite X-Porte Ultrasound System) and Predicate Device**

| Standard Feature | Sonosite X-Porte Ultrasound System (Subject Device) | Sonosite X-Porte Ultrasound System - K171437 (Predicate Device) | Comparison |
|---|---|---|---|
| **Indications for Use** | The SonoSite X-Porte Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: | The SonoSite X-Porte Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: | Identical |

| Standard Feature | Sonosite X-Porte Ultrasound System (Subject Device) | Sonosite X-Porte Ultrasound System - K171437 (Predicate Device) | Comparison |
|---|---|---|---|
| | Ophthalmic<br>Fetal – OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicles, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-vaginal<br>Musculo-skel. (Convent.)<br>Musculo-skel. (Superfic.)<br>Cardiac Adult<br>Cardiac Pediatric<br>Trans-esophageal (card.)<br>Peripheral Vessel | Ophthalmic<br>Fetal – OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicles, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-vaginal<br>Musculo-skel. (Convent.)<br>Musculo-skel. (Superfic.)<br>Cardiac Adult<br>Cardiac Pediatric<br>Trans-esophageal (card.)<br>Peripheral Vessel | |
| **Reusable?** | Yes | Yes | Identical |
| **Duration of Use** | Limited (<24 hours) | Limited (<24 hours) | Identical |
| **Scientific Technology** | Ultrasound Imaging | Ultrasound Imaging | Identical |
| **Operating Principle** | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | Identical |
| **Type of Previously Cleared Transducers** | Linear Array<br>Curved Linear Array<br>Intracavitary<br>Phased Array<br>Static Probes<br>Trans-esophageal | Linear Array<br>Curved Linear Array<br>Intracavitary<br>Phased Array<br>Static Probes<br>Trans-esophageal | Identical |
| **Acoustic Outputs Within Range?** | Yes | Yes | Identical |
| **Previously Cleared** | Yes | Yes | Identical |

| Standard Feature | Sonosite X-Porte Ultrasound System (Subject Device) | Sonosite X-Porte Ultrasound System - K171437 (Predicate Device) | Comparison |
|---|---|---|---|
| **Imaging Modes?** | | | |
| **Biocompatibility** | Per ISO 10993-1 | Per ISO 10993-1 | Identical |

**Table 5: Technological Comparison of Subject Device (Sonosite Edge II Ultrasound System) and Predicate Device**

| Standard Feature | Sonosite Edge II Ultrasound System (Subject Device) | Sonosite Edge II Ultrasound System - K162045 (Predicate Device) | Comparison |
|---|---|---|---|
| **Indications for Use** | The SonoSite Edge II Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal - OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicle, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-rectal<br>Trans-vaginal<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Cardiac Adult<br>Cardiac Pediatric<br>Trans-esophageal (cardiac)<br>Peripheral Vessel | The SonoSite Edge II Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:<br><br>Ophthalmic<br>Fetal - OB/GYN<br>Abdominal<br>Pediatric<br>Small Organ (breast, thyroid, testicle, prostate)<br>Neonatal Cephalic<br>Adult Cephalic<br>Trans-rectal<br>Trans-vaginal<br>Musculo-skeletal (Conventional)<br>Musculo-skeletal (Superficial)<br>Cardiac Adult<br>Cardiac Pediatric<br>Trans-esophageal (cardiac)<br>Peripheral Vessel | Identical |
| **Reusable?** | Yes | Yes | Identical |
| **Duration of Use** | Limited (<24 hours) | Limited (<24 hours) | Identical |
| **Scientific Technology** | Ultrasound Imaging | Ultrasound Imaging | Identical |
| **Operating Principle** | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate | Identical |

| Standard Feature | Sonosite Edge II Ultrasound System (Subject Device) | Sonosite Edge II Ultrasound System - K162045 (Predicate Device) | Comparison |
|---|---|---|---|
| | through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | |
| **Type of Previously Cleared Transducers** | Linear Array<br>Curved Linear Array<br>Intracavitary<br>Phased Array<br>Trans-esophageal | Linear Array<br>Curved Linear Array<br>Intracavitary<br>Phased Array<br>Trans-esophageal | Identical |
| **Acoustic Outputs Within Range?** | Yes | Yes | Identical |
| **Previously Cleared Imaging Modes?** | Yes | Yes | Identical |
| **Biocompatibility** | Per ISO 10993-1 | Per ISO 10993-1 | Identical |

**Table 6: Technological Comparison of Subject Device (Sonosite Maxx Ultrasound System) and Predicate Device**

| Standard Feature | Sonosite Maxx Ultrasound System (Subject Device) | Sonosite Maxx Ultrasound System - K130173 (Predicate Device) | Comparison |
|---|---|---|---|
| **Indications for Use** | The SonoSite Maxx Ultrasound System is a general-purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications include:<br>Ophthalmic, Fetal - OB/GYN, Abdominal, lntraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel. | The SonoSite Maxx Ultrasound System is a general-purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications include:<br>Ophthalmic, Fetal - OB/GYN, Abdominal, lntraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel. | Identical |

| Standard Feature | Sonosite Maxx Ultrasound System (Subject Device) | Sonosite Maxx Ultrasound System - K130173 (Predicate Device) | Comparison |
|---|---|---|---|
| | | | |
| **Reusable?** | Yes | Yes | Identical |
| **Duration of Use** | Limited (<24 hours) | Limited (<24 hours) | Identical |
| **Scientific Technology** | Ultrasound Imaging | Ultrasound Imaging | Identical |
| **Operating Principle** | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | The ultrasound beam originates from mechanical oscillations of numerous crystals in a transducer, which is excited by electrical pulses (piezoelectric effect). The ultrasound waves (pulses of sound) are sent from the transducer, propagate through different tissues, and then return to the transducer as reflected echoes. The returned echoes are converted back into electrical impulses by the transducer crystals and are further processed to form the ultrasound image presented on the screen. | Identical |
| **Type of Previously Cleared Transducers** | Linear Array<br>Curved Linear Array<br>Intracavitary<br>Phased Array<br>Static Probes<br>Trans-esophageal | Linear Array<br>Curved Linear Array<br>Intracavitary<br>Phased Array<br>Static Probes<br>Trans-esophageal | Identical |
| **Acoustic Outputs Within Range?** | Yes | Yes | Identical |
| **Previously Cleared Imaging Modes?** | Yes | Yes | Identical |
| **Biocompatibility** | Per ISO 10993-1 | Per ISO 10993-1 | Identical |

## VII. Standards Compliance

The standards compliance of the devices included in this application remains unchanged from the previously cleared devices. The expansion in labeling does not necessitate new testing or impact standards compliance in any way. A declaration of conformity that lists the recognized standards that the Sonosite suite of Ultrasound systems comply with is included with this submission.

## VIII. Performance Testing

Relevant performance data does not apply to this submission. Design control measures described within the submission support a decision of substantial equivalence.

## IX. Conclusions

There are no changes in software, hardware, and intended uses of the subject devices compared to the predicates. Additional user labeling has been included for the subject devices, including information about lung and cardiac ultrasound imaging, based on established methods or the latest society guidelines, for patients with coronavirus disease 2019 (COVID-19). The results of the design controls activity support a determination that the subject devices do not raise new questions of safety or effectiveness and are substantially equivalent to the predicate devices.