



SuperSonic Imagine, S.A.
% Mr. Laurence Hermitte
Quality & Regulatory Affairs Director
Les Jardins de la Duranne - Bât. E&F
510, rue René Descartes
13857 Aix-en-Provence Cedex
FRANCE

January 9, 2018

Re: K173021

Trade/Device Name: AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 30, 2017
Received: December 7, 2017

Dear Mr. Hermitte:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173021

Device Name

AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems

Indications for Use (Describe)

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, doppler fluid flow analysis of the human body.

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems are indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac.

In addition, the SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and associated transducers are intended for:- Measurements of abdominal anatomical structures,- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,- Measurements of brightness ratio between liver and kidney,- Visualization of abdominal vascularization, microvascularization and perfusion, - Quantification of abdominal vascularization and perfusion.

The shear wave speed and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion, the quantification of vascularization and perfusion may be used as an aid to clinical management of adult patients with liver disease.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use

510(k) number (if known):

Device Name: AIXPLORER® Ultrasound Diagnostic System

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

Clinical Application		B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
General (Track 1 Only)	Specific (Tracks 1 & 3)							
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P, 1, 3, 4, 11	P, 5, 6, 10
	Abdominal (including urology): Liver, Kidney, Spleen...	P	P	P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10, 11, 13, 14 - N 16
	Intra-operative (Specify) vascular, abdominal, small organs	P		P		P	P, 1, 3, 4	P, 5, 6, 9
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10 - N 16
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3, 4, 12	P, 5, 6, 7, 8, 9, 10, 14
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic	P		P		P	P, 1, 3, 4	P, 5, 6
	Trans-rectal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8
	Trans-vaginal	P	P	P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 11
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10, 14
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10, 14
	Intravascular							
	GYN	P	P	P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 11, 14
	Pelvic	P	P	P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 11, 14
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P		P	P, 1, 3, 4, 11	P, 5
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9, 10
Vessel	Other (Specify)	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

- 1: Combined modes include: B+ Color Flow
- 2: Combined modes include: B+ ShearWave™ Elastography
- 3: Combined modes include: B+ Pulsed Wave
- 4: Combined modes include: B+ Pulsed Wave + Color Flow
- 5: Harmonic Imaging
- 6: Spatial Compounding
- 7: ShearWave™ Elastography
- 8: Imaging Guidance for Biopsies

- 10: 3D Imaging
- 11: Combined modes include: B+ M modes
- 12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography
- 13: CEUS (Contrast Enhancement UltraSound)
- 14: Angio PL.U.S (Color Doppler improvement)
- 15: Needle PL.U.S
- 16: Brightness ratio

9: Panoramic Imaging

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SL10-2 transducer (linear transducer, SSIP92085)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 13,14, 15
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 15, N 16
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3, 4, 12	P, 5, 6, 7, 8, 9, 14, 15
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 14, 15
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 14, 15
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9, 15
Vessel	Other (Specify)	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9, 15

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

- | | |
|--|---|
| 1: Combined modes include: B+ Color Flow | 9: Panoramic Imaging |
| 2: Combined modes include: B+ ShearWave™ Elastography | 10: 3D Imaging |
| 3: Combined modes include: B+ Pulsed Wave | 11: Combined modes include: B+ M modes |
| 4: Combined modes include: B+ Pulsed Wave + Color Flow | 12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography |
| 5: Harmonic Imaging | 13: CEUS (Contrast Enhancement UltraSound) |
| 6: Spatial Compounding | 14: Angio PL.U.S (Color Doppler improvement) |
| 7: ShearWave™ Elastography | 15: Needle PL.U.S |
| 8: Imaging Guidance for Biopsies | 16: Brightness ratio |

Prescription Use ☒ X _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: XC6-1 transducer (curved array transducer, SSIP92167)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal	P	P	P		P	P, 1, 3, 4, 11	P 5, 6
	Abdominal (including urology), Liver, Kidney, Spleen.	P	P	P		P	P1, 2, 3, 4, 11	P 5, 6, 7, 8, 9, 13,14, N16
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 13, N16
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	P	P	P		P	P 1, 2, 3, 4	P 5, 6, 7, 8,14
	Pelvic	P	P	P		P	P1, 2, 3, 4	P 5, 6, 7, 8, 14
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P1, 3, 4	P 5, 6, 8
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

- | | |
|--|---|
| 1: Combined modes include: B+ Color Flow | 9: Panoramic Imaging |
| 2: Combined modes include: B+ ShearWave™ Elastography | 10: 3D Imaging |
| 3: Combined modes include: B+ Pulsed Wave | 11: Combined modes include: B+ M modes |
| 4: Combined modes include: B+ Pulsed Wave + Color Flow | 12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography |
| 5: Harmonic Imaging | 13: CEUS (Contrast Enhancement UltraSound) |
| 6: Spatial Compounding | 14: Angio PL.U.S (Color Doppler improvement) |
| 7: ShearWave™ Elastography | 15: Needle PL.U.S. |
| 8: Imaging Guidance for Biopsies | 16: Brightness ratio |

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SL15-4 transducer (1D Linear Array Transducer, SSIP92002)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 14
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P 1, 2, 3, 4, 12	P 5, 6, 7, 8, 9, 14
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 14
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 14
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 9
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SC6-1 transducer (curved array transducer, SSIP92030)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal	P	P	P		P	P 1, 3, 4, 11	P 5, 6
	Abdominal (including urology), Liver, Kidney, Spleen	P	P	P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 11
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Intravascular							
	GYN	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Pelvic	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 9
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use ☒ X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SE12-3 transducer (endocavitary transducer, SSIP92068 & SSIP93068)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal	P	P	P		P	P 1, 3, 4, 11	P 5, 6
	Abdominal (including urology): Liver, Kidney, Spleen...							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Trans-vaginal	P	P	P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 11
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	P	P	P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 11
	Pelvic	P	P	P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 11
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SLV16-5 transducer (motorized linear transducer, SSIP90055 & SSIP93055)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 10
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 10
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 10
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 10
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 10
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 9, 10
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use ____X____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SMC12-3 transducer (micro-curved transducer, SSIP92097)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P		P	P 1,3,4,5,11	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9
Vessel	Other (Specify)	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use ☒X_____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: XP5-1 transducer (Phased Array transducer, SSIP92161)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...	P		P		P	P 1, 3, 4	P 5, 6
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 3, 4	P 5, 6
	Neonatal Cephalic							
	Adult Cephalic	P		P		P	P 1, 3, 4	P 5, 6
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P		P	P1, 3, 4, 5, 11	
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SLH20-6 transducer (linear transducer, SSIP92164 & SSIP93164)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...							
	Intra-operative (Specify) Vascular, abdominal, small organs	P		P		P	P 1, 3, 4	P 5, 6, 9, 15
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 3, 4	P 5, 6, 9, 2, 7, 15
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 3, 4	P 5, 6, 9, 2, 7, 15
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 3, 4	P 5, 6, 9, 2, 7, 15
	Musculo-skeletal (Superficial)	P		P		P	P 1, 3, 4	P 5, 6, 9, 2, 7, 15
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 9, 15
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 9, 15

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Over-The-Counter Use

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SEV12-3 transducer (endocavitary transducer, SSIP92189)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal	P	P	P		P	P, 1, 3, 4, 11	P, 5, 6, 10
	Abdominal (including urology): Liver, Kidney, Spleen...							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Trans-vaginal	P	P	P		P	P1, 2, 3, 4, 11	P 5, 6, 7, 8, 10
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	P	P	P		P	P 1, 2, 3, 4, 11	P 5, 6, 7, 8, 10
	Pelvic	P	P	P		P	P 1, 2, 3, 4, 11	P 5, 6, 7, 8, 10
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

Prescription Use ☒ X _____

(Part 21 CFR 801 Subpart D)

AND/OR

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™

Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Over-The-Counter Use _____

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: SL18-5 transducer (1D Linear Array Transducer, SSIP92501)

Intended Use: Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body as follows:

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							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology): Liver, Kidney, Spleen...	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 14, 15
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 15
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P 1, 2, 3, 4 P 12	P 5, 6, 7, 8, 9, 14, 15
	Neonatal Cephalic	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 14, 15
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9, 14, 15
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 9, 15
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8, 9, 15

N = new indication; P = previously cleared by FDA (K171105)

Additional Comments:

1: Combined modes include: B+ Color Flow

2: Combined modes include: B+ ShearWave™ Elastography

3: Combined modes include: B+ Pulsed Wave

4: Combined modes include: B+ Pulsed Wave + Color Flow

5: Harmonic Imaging

6: Spatial Compounding

7: ShearWave™ Elastography

8: Imaging Guidance for Biopsies

9: Panoramic Imaging

10: 3D Imaging

11: Combined modes include: B+ M modes

12: Combined modes include: B Mode + Color flow + Shearwave™ Elastography

13: CEUS (Contrast Enhancement UltraSound)

14: Angio PL.U.S (Color Doppler improvement)

15: Needle PL.U.S.

Prescription Use ☒ X _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) Summary of Safety and Effectiveness

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

1) Submitter's name, address, telephone number, contact person

Submitted by:

SuperSonic Imagine, S.A.

Les Jardins de la Duranne – Bât. E & F

510, rue René Descartes

13857 Aix-en-Provence Cedex

France

Telephone: +33 442 99 24 24

Distributed by:

SuperSonic Imagine, Inc.

Weston

North America

Telephone: +1(954) 660 3528

Corresponding Official:

Jacques Souquet

Chief Innovation Officer

Telephone: +33 442 99 24 35

Date: 2017.09.15

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Ultrasound Diagnostic System with Accessories

Proprietary Name: AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems

Classification: Class II

Classification Name:	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Substantially Equivalent/Predicate Devices

AIXPLORER® Ultrasound Imaging System (K171105), cleared on 07/11/2017
GE LOGIC S8 including the FibroScan module (K170445), cleared on 04/11/2017
FibroScan (K160524), cleared on 03/18/2016

4) Description of Device

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate systems are a cart based ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging studies. The system contains a scan converter and can be coupled to a variety of linear, curved, micro-convex, and motorized linear and phased array transducers to produce images, which are displayed on a LCD monitor. An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles. The system also allows the user to perform measurements, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report. The system functions in a manner identical to the predicate devices and transducers for the imaging modes: B-Mode (harmonic or fundamental), M-mode, Color Flow (and sub-modes as CFI-ColorFlow Imaging, CPI-ColorPower Imaging- also called Amplitude Doppler, dCPI-directional Color Power Imaging and Angio PL.U.S), Pulsed Wave Doppler, 3D imaging, CEUS-Contrast Enhanced Ultrasound Imaging and for ShearWave™ elastography.

5) Indication for Use

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, doppler fluid flow analysis of the human body.

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems are indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal), Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac.

In addition, the SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and associated transducers are intended for:

- Measurements of abdominal anatomical structures,

- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,,
- Measurements of brightness ratio between liver and kidney,
- Visualization of abdominal vascularization, microvascularization and perfusion,
- Quantification of abdominal vascularization and perfusion

The shear wave speed and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion, the quantification of vascularization and perfusion may be used as an aid to clinical management of adult patients with liver disease.

6) Summary of Technological Characteristics – New Device compared to Predicates

	SuperSonic Imagine	GE	Echosens	SuperSonic Imagine
	SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate (predicates)	GE LOGIC S8 including the FibroScan module (predicate)	Fibroscan 530 Compact (predicate)	SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate
510(k) Number	K171105	K170445	K160524	Unassigned
Classification Name	Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Identical to K171105 and K170445
Class	Class II	Identical	Identical	Identical
Intended Use	Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Identical

	SuperSonic Imagine	GE	Echosens	SuperSonic Imagine
General Description	General purpose, mobile, software controlled diagnostic ultrasound system. To acquire ultrasound data and to display the data in various modes of operation.	Identical	Identical	Identical
	Consists of two parts: the system console and the transducer. The system console contains the user interface, a display, system electronics and optional peripherals (printers, etc...).	Identical	Identical	Identical
SWE Dynamic Range	Adjustable range capability and numeric display with scale	---	---	Identical to K171105
Clinical Applications	Abdominal	Identical	Identical	Identical
	Small organs	Identical	---	Identical to K171105 and K170445
	Musculoskeletal	Identical	---	Identical to K171105 and K170445
	Fetal	Identical	---	Identical to K171105 and K170445
	GYN	Identical	---	Identical to K171105 and K170445
	Cardiac	Identical	---	Identical to K171105 and K170445
	Adult and neonatal cephalic	Identical	---	Identical to K171105 and K170445

	SuperSonic Imagine	GE	Echosens	SuperSonic Imagine
	Pediatric	Identical	Identical	Identical
	Urology	Identical	---	Identical to K171105 and K170445
	Vascular	Identical	---	Identical to K171105 and K170445
	Peripheral vascular	Identical	---	Identical to K171105 and K170445
	Intraoperative	Identical	---	Identical to K171105 and K170445
	Trans-rectal	Identical	---	Identical to K171105 and K170445
	Trans-vaginal	Identical	---	Identical to K171105 and K170445
Imaging modes				
Conventional	B-Mode (Harmonic, Fundamental)	Identical	---	Identical to K171105 and K170445
	M-Mode	Identical	Identical	Identical
	PW	Identical	---	Identical to K171105 and K170445
	CW	Identical	---	Identical to K171105 and K170445
	Color Doppler	Identical	---	Identical to K171105 and K170445
	Amplitude Doppler	Identical	---	Identical to K171105 and K170445
	Microvascular (Angio PL.U.S)	---	---	Identical to K171105
Other	Spatial compounding, Panoramic	Identical	---	Identical to K171105 and K170445

	SuperSonic Imagine	GE	Echosens	SuperSonic Imagine
	Contrast	Identical	---	Identical to K171105 and K170445
	Combination of modes	Identical	--- (has specific modes: A-mode, CAP).	Identical to K171105 and K170445
	ShearWave Elastography	Identical	VCTE	Identical to K171105 and K170445
Design				
Cart	Mobile cart based product with control panel and monitor	Identical	Identical	Identical
Controls	Typical ultrasound imaging controls (gain, depth mode select...)	Identical	Identical	Identical
Biopsy guide	Available	Identical	---	Identical to K171105 and K170445
Track	Track 3 (Acoustic Output Display)	Identical	Identical	Identical
Patient Contact Materials	Yes, per ISO 10993-1	Identical	Identical	Identical
Acoustic Output within FDA guidelines	Yes, as per NEMA UD-3	Identical	Identical	Identical
Image Review	Yes	Identical	Identical	Identical
Measurement Package	Yes	Identical	Identical	Identical
Calculation Package	Yes	Identical	Identical	Identical

	SuperSonic Imagine	GE	Echosens	SuperSonic Imagine
Report	Yes	Identical	Identical	Identical
General Safety	Conforms to IEC60601-1, 60601-1-2, 60601-2-37	Identical	Identical	Identical
Labeling	Conforms to 21 CFR Part 801	Identical	Identical	Identical

Note:

*: Breast, Thyroid, Testicle, etc

**: --- means not applicable

7) A brief discussion of the non clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Non-clinical testing was conducted per the following standards to support a determination of substantial equivalence to the predicate devices.

Reference Standard	Tests Performed
IEC 60601-1 3.1 Edition	All applicable electrical, basic safety and essential performance tests.
IEC 60601-1-2 3 rd Edition	All applicable testing pertaining to electromagnetic compatibility.
IEC 60601-2-37 2 nd Edition	All applicable testing pertaining to the particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
NEMA UD 2 (Rev. 3)	All tests applicable in order to demonstrate compliance with the “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment”.
NEMA UD 3 (Rev. 2)	All tests applicable in order to demonstrate compliance with the “Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment”.
ISO 10993-1	Applicable biocompatibility tests per FDA 510(k) Memorandum - #G95-1 – per the appropriate device category.

The above testing confirmed that the Aixplorer® and Aixplorer® Ultimate Systems perform according to the stated intended use. All data fell within pre-determined product specifications and external standard requirements. Results of non-clinical testing confirmed the substantial equivalence of the Aixplorer® and Aixplorer® Ultimate Systems to the predicate device(s).

8) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

The subject of this premarket submission required a clinical evaluation by literature route to support substantial equivalence and to widen the indications for use of Aixplorer® and Aixplorer® Ultimate Ultrasound Diagnostic Systems.

9) Conclusion

The manufacturer and the design and development of the submission device comply with 21 CFR Part 820 and ISO 13485 (2003) Quality Standards. The submission device, designed to comply with applicable safety standards, is tested during the manufacturing process to ensure compliance with these standards. Performance testing demonstrated that the submission device is at least as safe and effective as the predicate devices listed in item 3.