



SuperSonic Imagine
% Laurence Hermitte
Quality & Regulatory Affairs Director
Les jardins de la Duranne - Bat E&F - 510 rue Rene Descartes
Aix-en-Provence, 13857
FRANCE

May 29, 2018

Re: K180572

Trade/Device Name: AIXPLORER[®] MACH Ultrasound Diagnostic Systems AIXPLORER[®]
MACH 30, AIXPLORER[®] MACH 20, AIXPLORER[®] MACH 10

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: March 8, 2018

Received: March 12, 2018

Dear Laurence 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,



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)

K180572

Device Name

AIXPLORER MACH Ultrasound Diagnostic Systems

AIXPLORER MACH 30, AIXPLORER MACH 20, AIXPLORER MACH 10

Indications for Use (Describe)

The SuperSonic Imagine AIXPLORER® MACH 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® MACH 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® MACH 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 and pediatric 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® MACH 30 (SSIP95030), AIXPLORER® MACH 20 (SSIP95020) and AIXPLORER® MACH 10 (SSIP95010) Ultrasound Diagnostic Systems

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

Clinical Application						Color Doppler	Combined (Specify)	Other* (Specify)
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD			
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N 1, 3, 4, 11	N 5, 6, 10
	Abdominal (including urology): Liver, Kidney, Spleen...	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10, 11, 13, 14, 16
	Intra-operative (Specify) vascular, abdominal, small organs	N		N		N	N 1, 3, 4	N 5, 6, 8, 9
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10, 11, 13, 16
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N 1, 2, 3, 4, 12	N 5, 6, 7, 8, 9, 10, 14
	Neonatal Cephalic	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 9
	Adult Cephalic	N		N		N	N 1, 3, 4	N 5, 6
	Trans-rectal	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8
	Trans-vaginal	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 11
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10, 14
	Musculo-skeletal (Superficial)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10, 14
	Intravascular							
	GYN	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 11, 14
	Pelvic	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 11, 14
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N	N	N	N 1, 3, 4, 11, 17, 18	N, 5
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N, 1, 3, 4	N, 5, 6, 8, 9, 10
Vessel	Other (Specify)	N		N		N	N, 1, 3, 4	N, 5, 6, 8, 9, 10

N = new indication;

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 mode
- 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
- 17: Combined mode include: B+ Continuous Wave
- 18: Combined mode include: B+ M mode + Color flow

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)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: L10-2 transducer (SSIP95103)

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...	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9, 13, 14, 15, 16
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9, 15, 16
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N, 1, 2, 3, 4, 12	N, 5, 6, 7, 8, 9, 14, 15
	Neonatal Cephalic	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9, 14, 15
	Musculo-skeletal (Superficial)	N		N		N	N, 1, 2, 3, 4	N, 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	N		N		N	N, 1, 3, 4	N, 5, 6, 8, 9, 15
Vessel	Other (Specify)	N		N		N	N, 1, 3, 4	N, 5, 6, 8, 9, 15

N = new indication;

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 mode

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

17: Combined mode include: B+ Continuous Wave

18: Combined mode includes: B+ M mode + Color flow

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: C6-1X transducer (SSIP95101)

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	N	N	N		N	N 1, 3, 4, 11	N 5, 6
	Abdominal (including urology), Liver, Kidney, Spleen.	N	N	N		N	N 1, 2, 3, 4, 11	N 5, 6, 7, 8, 9, 13,14, 16,
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 13,16
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N 1, 2, 3, 4	N 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	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 14
	Pelvic	N	N	N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 14
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N 1, 3, 4	N 5, 6, 8
Vessel	Other (Specify)	N		N		N	N 1, 3, 4	N 5, 6, 8

N = new indication;

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode includes: B+ M mode + Color flow

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: E12-3 transducer (SSIP95102)

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	N	N	N		N	N 1, 3, 4, 11	N 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...)	N		N		N	N1, 2, 3, 4	N 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8
	Trans-vaginal	N	N	N		N	N1, 2, 3, 4, 11	N5, 6, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	N	N	N		N	N 1, 2, 3, 4, 11	N 5, 6, 7, 8
	Pelvic	N	N	N		N	N1, 2, 3, 4, 11	N 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)	N		N		N	N 1, 3, 4	N 5, 6, 8

N = new indication; N

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode included: B+ M mode + Color flow

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)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: LV16-5 transducer (SSIP95108)

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...	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 10
	Musculo-skeletal (Superficial)	N		N		N	N 1, 2, 3, 4	N 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	N		N		N	N 1, 3, 4	N 5, 6, 8, 9, 10
Vessel	Other (Specify)							

N = new indication;

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode includes: B+ M mode + Color flow

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)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: MC12-3 transducer (SSIP95106)

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...	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9, 13
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9, 13
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9
	Neonatal Cephalic	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	N		N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N		N	N 1,3,4,11	N, 5, 6
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N, 1, 3, 4	N, 5, 6, 8, 9
Vessel	Other (Specify)	N		N		N	N, 1, 3, 4	N, 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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode included: B+ M mode + Color flow

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: P5-1X transducer (SSIP95107)

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...	N	N	N	N	N	N 1, 3, 4, 11, 17	N 5, 6, 16
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N 1, 3, 4	N 5, 6
	Neonatal Cephalic							
	Adult Cephalic	N		N		N	N 1, 3, 4	N 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	N	N	N	N	N	N 1, 3, 4, 11, 17, 18	N, 5, 6
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N	N	N	N 1, 3, 4, 17	N 5, 6
Vessel	Other (Specify)	N		N	N	N	N 1, 3, 4, 17	N 5, 6

N = new indication; N

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode includes: B+ M mode + Color flow

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: LH20-6 transducer (SSIP95104)

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	N		N		N	N 1, 3, 4	N 5, 6, 915
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 915
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 915
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 915
	Musculo-skeletal (Superficial)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 915
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N 1, 3, 4	N 5, 6, 915
Vessel	Other (Specify)	N		N		N	N 1, 3, 4	N 5, 6, 915

N = new indication;

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode included: B+ M mode + Color flow

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)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: L18-5 transducer (SSIP95100)

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...	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9, 1415
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 91515
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	N		N		N	N 1, 2, 3, 4, 12	N 5, 6, 7, 8, 9, 14
	Neonatal Cephalic	N		N		N	N1, 2, 3, 4	N 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9,1415
	Musculo-skeletal (Superficial)	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 9,1415
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N 1, 3, 4	N 5, 6, 8, 915
Vessel	Other (Specify)	N		N		N	N 1, 3, 4	N 5, 6, 8, 915

N = new indication;

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode included: B+ M mode + Color flow

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)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: C9-2X (SSIP95105)

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	N	N	N		N	N 1, 3, 4, 11	N 5, 6
	Abdominal (including urology): Liver, Kidney, Spleen...	N	N	N		N	N 1, 2, 3, 4, 11	N 5, 6, 7, 8, 9, 13, 14, 16
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N 1, 2, 3, 4	N 5, 6, 7, 8, 13, 16
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	N		N		N	N 1, 2, 3, 4	N 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	N	N	N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 14
	Pelvic	N	N	N		N	N, 1, 2, 3, 4	N, 5, 6, 7, 8, 14
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N, 1, 3, 4	N, 5, 6, 8
Vessel	Other (Specify)	N		N		N	N, 1, 3, 4	N, 5, 6, 8

N = new indication;

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.

16: Brightness ratio

17: Combined mode include: B+ Continuous Wave

18: Combined mode includes: B+ M mode + Color flow

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)

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: 2018.02.09

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® MACH Ultrasound Diagnostic Systems

AIXPLORER® MACH 30, AIXPLORER® MACH 20, AIXPLORER® MACH 10

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 (K173021), cleared on 01/09/2018

FibroScan (K160524), cleared on 03/18/2016

Epiq 7 (K163120) cleared on 01/10/2017

4) Description of Device

The SuperSonic Imagine AIXPLORER® MACH systems are cart based ultrasound imaging systems 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, Continuous Wave Doppler, 3D imaging, CEUS-Contrast Enhanced Ultrasound Imaging and for ShearWave™ elastography.

5) Indication for Use

The SuperSonic Imagine AIXPLORER® MACH 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® MACH 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® MACH range 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, the spleen and other biological tissue in the abdomen,
- Measurements of brightness ratio between liver, kidney, and other biological structures of the abdomen,
- 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 pediatric and adult patients with liver disease.

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

	AIXPLORER® & AIXPLORER® Ultimate (predicates)	EPIQ 7 (predicate)	FibroScan® 530 Compact (predicate)	AIXPLORER® MACH range
510(k) Number	K173021	K163120	K160524	Unassigned
Classification Name	Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Identical to K173021	Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Identical to K173021
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 to K173021
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
Clinical Applications	Abdominal (liver, kidney, spleen)	Identical	Identical	Identical
	Small organs (*)	Identical	--	Identical

	AIXPLORER® & AIXPLORER® Ultimate (predicates)	EPIQ 7 (predicate)	FibroScan® 530 Compact (predicate)	AIXPLORER® MACH range
	Musculoskeletal	Identical	--	Identical
	Fetal	Identical	--	Identical
	GYN	Identical	--	Identical
	Cardiac (non invasive)	Cardiac	--	Identical to K173021
	Adult and neonatal cephalic	Identical	--	Identical
	Pediatric	Identical	Identical	Identical
	Urology	Identical	--	Identical
	Vascular	Identical	--	Identical
	Peripheral vascular	Identical	--	Identical
	Trans-rectal	Identical	--	Identical
	Trans-vaginal	Identical	--	Identical
Imaging modes				
Conventional	B-Mode (Harmonic, Fundamental)	Identical	--	Identical
	M-Mode	Identical	Identical	Identical
	PW	Identical	--	Identical
	-	CW	--	Identical to K163120
	Color Doppler	Identical	--	Identical
	Amplitude Doppler	Identical	--	Identical
	Microvascular (Angio PL.U.S)	---(**)	--	Identical to K173021
Other	Spatial compounding, Panoramic	Identical	--	Identical
	Contrast	Identical	--	Identical

	AIXPLORER® & AIXPLORER® Ultimate (predicates)	EPIQ 7 (predicate)	FibroScan® 530 Compact (predicate)	AIXPLORER® MACH range
	Combination of modes	Identical	--- (has specific modes: A-mode, CAP).	Identical
	ShearWave Elastography	Identical	VCTE	Identical
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
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
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 Ed.3.1	All applicable electrical, basic safety and essential performance tests.
IEC 60601-1-2 Ed.4	All applicable testing pertaining to electromagnetic compatibility.
IEC 60601-2-37 Ed.2.1	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® MACH 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® MACH 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® MACH range 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 (2016) 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.