SuperSonic Imagine
% Jacques Souquet
Chief Innovation Officer
Les Jardins de la Duranne – Bât. E&F
510, rue René Descartes
13857 Aix-en-Provence Cedex
FRANCE

December 29, 2020

Re: K202455
Trade/Device Name: AIXPLORER® MACH 20, AIXPLORER® MACH 30, SUPERSONIC MACH40, SUPERSONIC MACH30 & SUPERSONIC MACH20 Ultrasound Diagnostic Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 12, 2020
Received: December 18, 2020

Dear Jacques Souquet:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202455

Device Name
AIXPLORER® MACH 20, AIXPLORER® MACH 30, SUPERSONIC MACH40, SUPERSONIC MACH30 & SUPERSONIC MACH20 Ultrasound Diagnostic Systems

Indications for Use *(Describe)*
The SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH range ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue viscoelasticity imaging, doppler fluid flow analysis of the human body.

The SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC 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 shearwave speed, beam attenuation, viscosity 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.

The supported clinical applications for contrast enhancement imaging does not constitute permission to do such imaging beyond the scope of the contrast agent.

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.

Diagnostic Ultrasound Indications for Use

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Device Name: AIXPLORER® MACH 30 (SSIP95030) , AIXPLORER® MACH 20 (SSIP95020), SUPERSONIC MACH30 (SSIP95030-HOLX), SUPERSONIC MACH20 (SSIP95020-HOLX) & SUPERSONIC MACH40 (SSIP95040) Ultrasound Diagnostic Systems

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

Clinical Application								
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 urolology): Liver, Kidney, Spleen…	P	P	P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8, 9, 10, 11,13, 14, 15, 16 – N: 21,22
	Intra-operative (Specify) vascular, abdominal, small organs	P		P		P	P : 1, 3, 4	P: 5, 6, 8, 9
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8, 9, 10, 11, 13, 15, 16 – N: 14, 18, 19, 21, 20
	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, 15, 18, 19, 20, 21 N : 13
	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 N : 13
	Trans-vaginal	P	P	P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8, 11 N : 13
	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, 15,19, 20 N : 13
	Musculo-skeletal (Superficial)	P		P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8, 9, 10, 14, 15,19, 20 N : 13
	Intravascular							
	GYN	P	P	P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8 11, 14 N : 13
	Pelvic	P	P	P		P	P : 1, 2, 3, 4	P: 5, 6, 7, 8,11, 14 N : 13
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P : 1, 3, 4, 11, 17, 18	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, 15 N : 13
Vessel	Other (Specify)	P		P		P	P : 1, 3, 4	P : 5, 6, 8, 9, 10, 15 N : 13

N = new indication; P = Previously cleared by FDA (K191007)

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 Enhancement UltraSound)
13: CEUS (Contrast)
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 19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE 21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

Device Name: L10-2 transducer (linear 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 urolology): Liver, Kidney, Spleen…	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 13,14, 15, 16 – N: 21,22
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9,14,15,16, 21, 22 N : 13
	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, 15,20, 21, 22 N : 13
	Neonatal Cephalic	P		P		P	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)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 14,15,20 N : 13
	Musculo-skeletal (Superficial)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 14, 15,20 N : 13
	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 N : 13
Vessel	Other (Specify)	P		P		P	P: 1, 3, 4	P: 5, 6, 8, 9, 15 N : 13

N = new indication; P = Previously cleared by FDA (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: C6-1X transducer (curved array 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	P	P	P		P	P : 1, 3, 4, 11	P : 5, 6
	Abdominal (including urolology), Liver, Kidney, Spleen.	P	P	P		P	P: 1, 2, 3, 4, 11	P: 5, 6, 7, 8, 9, 13,14, 16, 21, 22
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 13, 14, 16, 21, 22
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8 N : 13
	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, 8,11,14 N : 13
	Pelvic	P	P	P		P	P 1, 2, 3, 4	P: 5, 6, 7, 8, 11,14 N : 13
	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 N : 13
Vessel	Other (Specify)	P		P		P	P: 1, 3, 4	P: 5, 6, 8 N : 13

N = new indication; P = Previously cleared by FDA (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: E12-3 transducer (endocavitary 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	P	P	P		P	P : 1, 3, 4, 11	P : 5, 6
	Abdominal (including urolology): 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 N : 13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8 N : 13
	Trans-vaginal	P	P	P		P	P: 1, 2, 3, 4, 11	P: 5, 6, 7, 8 N : 13
	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 N : 13
	Pelvic	P	P	P		P	P: 1, 2, 3, 4, 11	P: 5, 6, 7, 8 N : 13
	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 : 13

N = new indication; P = Previously cleared by FDA (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: LV16-5 transducer (motorized linear 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 urolology): 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 (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: MC12-3 transducer (micro-curved 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 urolology): Liver, Kidney, Spleen…	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 13
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 13
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	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: 1,3,4,11	P: 5, 6
	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 (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: P5-1X transducer (Phased Array 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 urolology): Liver, Kidney, Spleen…	P	P	P	P	P	P: 1, 3, 4, 11, 17	P: 5, 6, 16
	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	P	P : 1, 3, 4, 11, 17, 18	P: 5, 6
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P	P	P	P: 1, 3, 4, 17	P: 5, 6
Vessel	Other (Specify)	P		P	P	P	P: 1, 3, 4, 17	P: 5, 6

N = new indication; P = Previously cleared by FDA (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: LH20-6 transducer (linear 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 urolology): 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, 2, 3, 4	P: 5, 6, 7, 9, 15
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 9, 15
	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, 9, 15
	Musculo-skeletal (Superficial)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 9, 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 (K191007)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: L18-5 transducer Linear Array 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 urolology): 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, 14, 15
	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 – N: 19, 20
	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 – N: 19, 20
	Musculo-skeletal (Superficial)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9,14, 15 – N: 19, 20
	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 (K180572)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):

Device Name: C9-2X transducer Curved Array transducer, 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	P	P	P		P	P: 1, 3, 4, 11	P: 5, 6
	Abdominal (including urolology): Liver, Kidney, Spleen…	P	P	P		P	P: 1, 2, 3, 4, 11	P: 5, 6, 7, 8, 9, 13, 14, 16 - N: 21, 22
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 13, 16 – N: 21, 22
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8 N : 13
	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 N : 13
	Pelvic	P	P	P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 14 N : 13
	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 N : 13
Vessel	Other (Specify)	P		P		P	P: 1, 3, 4	P: 5, 6, 8 N : 13

N = new indication; P = Previously cleared by FDA (K180572)

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
19: Strain Elastography
20: Combined mode: B Mode + Strain + SWE
21: Vi PLUS
22: Att PLUS & SSp PLUS

510(k) Summary of Safety and Effectiveness

K202455

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

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Date: 2020.12.22

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 20, AIXPLORER® MACH 30, SUPERSONIC MACH40, SUPERSONIC MACH30 & SUPERSONIC MACH20 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® MACH 20, AIXPLORER® MACH 30 Ultrasound Diagnostic Systems (K191007), cleared on 10/25/2019

4) Description of Device

The SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC 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 and Strain Elastography.

5) Indication for Use

The SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH range ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue viscoelasticity imaging, doppler fluid flow analysis of the human body.
The SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC 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 shearwave speed, beam attenuation, viscosity 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.

The supported clinical applications for contrast enhancement imaging does not constitute permission to do such imaging beyond the scope of the contrast agent.

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

	SuperSonic Imagine	SuperSonic Imagine
	Aixplorer MACH range sw V2 (predicates)	AIXPLORER® MACH / SUPERONIC MACH range sw V2
510(k) Number	K191007	Unassigned
Classification Name	Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Identical
Class	Class II	Identical
Intended Use	Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body	Identical
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
	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
Clinical Applications	Abdominal (liver, kidney, spleen)	Identical
	Small organs (*)	Identical
	Musculoskeletal	Identical
	Fetal	Identical
	GYN	Identical
	Cardiac (non invasive)	Identical
	Adult and neonatal cephalic	Identical

	SuperSonic Imagine	SuperSonic Imagine
	Pediatric	Identical
	Urology	Identical
	Vascular	Identical
	Peripheral vascular	Identical
	Trans-rectal	Identical
	Trans-vaginal	Identical
Imaging modes		
Conventional	B-Mode (Harmonic, Fundamental)	Identical
	M-Mode	Identical
	PW	Identical
	CW	Identical
	Color Doppler	Identical
	Amplitude Doppler	Identical
	Microvascular (Angio PL.U.S)	Identical
Other	Spatial compounding, Panoramic	Identical
	Contrast	Identical Addition of Contrast availability on clinical applications.
	Combination of modes	Identical
	ShearWave Elastography	Identical
	Strain Elastography	Identical
Design		
Cart	Mobile cart based product with control panel and monitor	Identical
Controls	Typical ultrasound imaging controls (gain, depth mode select…)	Identical
Biopsy guide	Available	Identical

	SuperSonic Imagine	SuperSonic Imagine
Track	Track 3 (Acoustic Output Display)	Identical
Patient Contact Materials	Yes, per ISO 10993-1	Identical
Acoustic Output within FDA guidelines	Yes, as per NEMA UD-3	Identical
Image Review	Yes	Identical
Measurement Package	Yes	Identical
Calculation Package	Yes	Identical
Report	Yes	Identical
General Safety	Conforms to IEC60601-1, 60601-1-2, 60601-2-37	Identical
Labeling	Conforms to 21 CFR Part 801	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 "Accoustic 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 / SUPERSONIC 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

Not applicable.

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.