SuperSonic Imagine
℅ Jacques Souquet
Chief Scientist and Innovation Officer
Les Jardins de la Duranne- Bat E et F
510 rue René Descartes
13857Aix-en-Provence
FRANCE

June 29, 2021

Re: K203645
Trade/Device Name: AIXPLORER® MACH30/ SUPERSONIC MACH30, AIXPLORER® MACH20/ SUPERSONIC MACH20, SUPERSONIC MACH40
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 12, 2021
Received: April 16, 2021

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)*
K203645

Device Name
AIXPLORER® MACH 30 / SUPERSONIC MACH30, AIXPLORER® MACH 20 / SUPERSONIC MACH20 and SUPERSONIC MACH 40

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 / SUPERSONIC 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.

Furthermore, the SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH ultrasound diagnostic systems and associated transducers are intended for:
- Measurements of breast anatomical structures
- Measurements of broad band shear waves speed and tissue stiffness in internal structures of the breast
- Visualization of breast structures and micro-vascularization
- Visualization of breast masses morphology using shearwave elastography and micro-vascularization 2D mapping

The shear waves speed and stiffness measurements may be used as an aid to management of women patients with breast masses, as shearwave elastography in conjunction with 2D gray scale imaging and vascularization provides added information to better characterize breast masses and improve the diagnostic accuracy of ultrasound.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Diagnostic Ultrasound Indications for Use

510(k) number (if known): K203645
Device Name: AIXPLORER® MACH 30 / SUPERSONIC MACH30, AIXPLORER® MACH 20 / SUPERSONIC MACH20, SUPERSONIC MACH40
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, 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, 14, 18, 19, 21,22
	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
	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, 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, 15, 19, 20
	Musculo-skeletal (Superficial)	P		P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8, 9, 10, 14, 15, 19, 20
	Intravascular							
	GYN	P	P	P		P	P : 1, 2, 3, 4	P : 5, 6, 7, 8 11, 14
	Pelvic	P	P	P		P	P : 1, 2, 3, 4	P: 5, 6, 7, 8,11, 14
	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
Vessel	Other (Specify)	P		P		P	P : 1, 3, 4	P : 5, 6, 8, 9, 10, 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

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): K203645
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, 21,22
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 15, 16, 14, 21, 22
	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, 19, 20, 21, 22
	Neonatal Cephalic	P		P		P	N, 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, 19, 20
	Musculo-skeletal (Superficial)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9, 14, 15, 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 (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

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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, 13,16, 9, 14, 21, 22
	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, 11
	Pelvic	P	P	P		P	P 1, 2, 3, 4	P: 5, 6, 7, 8, 14, 11
	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
Vessel	Other (Specify)	P		P		P	P: 1, 3, 4	P: 5, 6, 8

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

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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
	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, 11	P: 5, 6, 7, 8
	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
	Pelvic	P	P	P		P	P: 1, 2, 3, 4, 11	P: 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)	P		P		P	P: 1, 3, 4	P: 5, 6, 8

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

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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)							

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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

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): K203645
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

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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, 915
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 915
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 915
	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

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

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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, 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, 19, 20
	Musculo-skeletal (Superficial)	P		P		P	P: 1, 2, 3, 4	P: 5, 6, 7, 8, 9,14, 15, 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 (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

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

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K203645
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, 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
	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	P: 1, 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	P: 1, 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 (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

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) Summary of Safety and Effectiveness K203645

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:

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Date: 2020.11.30

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 30 / SUPERSONIC MACH30,
AIXPLORER® MACH 20 / SUPERSONICMACH20,
SUPERSONIC MACH40

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

Primary Predicate Device	AIXPLORER® MACH range Ultrasound Imaging System (K191007), cleared on 10/25/2019
Reference devices	Aplio i900, i800, i700 V2 (K173090), cleared on 01/11/2018
	Resona 7 (K171233) cleared on 09/12/2017

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 submodes 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, OBGYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac. In addition, the SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC 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.

Furthermore, the SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH ultrasound diagnostic systems and associated transducers are intended for:

- Measurements of breast anatomical structures
- Measurements of broad band shear waves speed and tissue stiffness in internal structures of the breast
- Visualization of breast structures and micro-vascularization
- Visualization of breast masses morphology using shearwave elastography and micro-vascularization 2D mapping

The shear waves speed and stiffness measurements may be used as an aid to management of women patients with breast masses, as shearwave elastography in conjunction with 2D gray scale imaging and vascularization provides added information to better characterize breast masses and improve the diagnostic accuracy of ultrasound.

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

	SuperSonic Imagine	Canon Medical System	Mindray medical International	SuperSonic Imagine
	Aixplorer MACH range sw V2 (Primary Predicate Device)	Aplio i900, i800 and i700 V2.0 (Reference Device)	Resona 7 (Reference Device)	AIXPLORER® MACH / SUPERSONIC MACH range sw V3
510(k) Number	K191007	K173090	K171233	K203645
Classification Name	Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Identical	Identical	Identical
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 K191007
Indication for use	The SuperSonic Imagine AIXPLORER® MACH range ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue viscoelasticity imaging, doppler fluid flow analysis	The diagnostic ultrasound systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700, Aplio i600 Model TUS-AI600, are indicated for the visualisation of structures, and dynamic processes with the human body using ultrasound and to provide image	The Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intra-operative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes),	Identical to primary Predicate Device K191007 The SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH range ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft

	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, Noninvasive 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,	information for diagnosis in the following applications : fetal, abdominal, intraoperative (abdominal), pediatric, small organs, transvaginal, transrectal, neonatal cephalic, adult cephalic, cardica (both adult and pediatric), peripheral vascular, transoesophageal, musculoskeletal (both conventionnal and supercifical) and laparoscopic.	neonatal cephalic, adult cephalic, trans-rectal, transvaginal,musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, transesoph. (cardiac), peripheral vessel and urology exams.	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, Noninvasive Cardiac. In addition, the SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH ultrasound diagnostic systems and associated transducers are intended for: - Measurements of abdominal anatomical structures,

	- Measurements of brightness ratio between liver and kidney, - Visualization of abdominal vascularization, microvascularizati on 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.			- 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, microvascularizati on and perfusion, - Quantification of abdominal vascularization and perfusion. The shearwave speed, beam attenuation, viscosity and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularizati on 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. *Expansion for K203645* Furthermore, the SuperSonic Imagine AIXPLORER® MACH / SUPERSONIC MACH ultrasound diagnostic systems and associated

				transducers are intended for: - Measurements of breast anatomical structures - Measurements of broad band shear waves speed and tissue stiffness in internal structures of the breast - Visualization of breast structures and microvascularization -Visualization of breast masses morphology using shearwave elastography and microvascularization 2D mapping
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	Identical

	Musculoskeletal	Identical	Identical	Identical

	Fetal	Identical	Identical	Identical
	GYN	Identical	Identical	Identical
	Cardiac (non invasive)	Cardiac	Identical	Identical to K191007
	Adult and neonatal cephalic	Identical	Identical	Identical
	Pediatric	Identical	Identical	Identical
	Urology	Identical	Identical	Identical
	Vascular	Identical	Identical	Identical
	Peripheral vascular	Identical	Identical	Identical
	Trans-rectal	Identical	Identical	Identical
	Trans-vaginal	Identical	Identical	Identical
Imaging modes				
Conventional	B-Mode (Harmonic, Fundamental)	Identical	Identical	Identical
	M-Mode	Identical	Identical	Identical
	PW	Identical	Identical	Identical
	CW	CW	Identical	Identical to K191007

	Color Doppler	Identical	Identical	Identical
	Amplitude Doppler	Identical	Identical	Identical
	Microvascular (Angio PL.U.S)	---(**)	--	Identical to K191007

Other	Spatial compounding, Panoramic	Identical	Identical	Identical
	Contrast	Identical	Identical	Identical
	Combination of modes	Identical	Identical	Identical
	ShearWave Elastography	Identical	Identical	Identical
	Strain Elastography	Identical	Identical	Identical to K191007
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	Available	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, 60601-12, 606012-37	Identical	Identical	Identical
Labeling	Conforms to 21 CFR Part 801			Conforms to 21 CFR Part 801 The user interface includes a dedicated menu for Bi-Rads. This menu provides Bi-Rads lexicon classification which allows the user to classify the lesion according to Bi-Rads criteria.
				Bi-RADS (ACR***) lexicon classification User Interface is composed of following information : - Tissue Composition - Masses : • Shape • Orientation • Margin • Echo Pattern These information are criteria for lesion characterization according to Bi-RADS scoring to assess the risk of lesion malignancy.

Note:

*: Breast, Thyroid, Testicle, etc
**:--- means not applicable
*** American College of Radiology

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 AiIXPLORER® 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 / SUPERSONIC 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 / SUPERSONIC MACH range Ultrasound Diagnostic Systems. Summary of literature review : Owing to its correlation with cancer risk, real-time mapping of breast lesions stiffness has proven to produce important information to breast physicians that can improve the global management patients with breast lesions. Addition of Shear Wave elastography to conventional B-mode Ultrasound increased the specificity of breast mass assessment. It can significantly improve the positive predictive value of biopsy recommendation for probably benign and low suspicion breast lesions on ultrasound, while preserving the sensitivity of breast ultrasound. This benefit has been demonstrated in diagnostic settings. The addition of SWE evaluation of breast lesions also increases the inter-observer agreement on their global cancer risk assessment with ultrasound, thanks to its “almost perfect” intra-operator repeatability and high inter-observer reproducibility. The evaluation of breast cancers with SWE seem to contribute to defining more appropriate management strategies thanks to more accurate cancer size measurements, to correlation with cancer aggressiveness and response to neo-adjuvant chemotherapy treatment.

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.