



October 28, 2022

SuperSonic Imagine  
% Shalyna Bansropun  
Regulatory Affairs Manager  
Zac de l'enfant 135 rue Emilien Gautier  
Aix en Provence, 13290  
FRANCE

Re: K222191

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: September 23, 2022

Received: September 28, 2022

Dear Shalyna Bansropun:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna Kang, Ph.D.  
Assistant Director  
Mammography and Ultrasound Team  
DHT8C: Division of Radiological Imaging  
and Radiation Therapy Devices  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K222191

Device Name

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

Indications for Use (Describe)

The Hologic SuperSonic Imagine 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 Hologic SuperSonic SUPERSONIC MACH range 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.

Modes of operation include: B-mode [2D ; 3D ; Panoramic Imaging; Spatial Compounding ], M-mode , Doppler [Continuous Wave (CW); Pulsed Wave (PW); Color and Power Doppler (Color Flow Imaging), Color Doppler (Angio PL.U.S) ], Strain Elastography, Tissue Harmonic Imaging, Contrast Enhanced Ultrasound Imaging (CEUS); ShearWave Elastography (SWE); ShearWave dispersion Viscosity (Vi PLUS); Combination Modes [ (B/Color Flow) ; (B/SWE), ( B/PW), (B/PW/Color Flow); (B/ M-mode); (B/Color flow/SWE); (B/CW) ; (B/M-mode/Color flow); (B/Strain Elastography/SWE)].

In addition, the Hologic SuperSonic Imagine SUPERSONIC 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 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 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.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to use or direct the use of the device. This device is intended for use in hospital environment or physician's office.

This system should only be used by trained Health Care Professionals (HCP) who are knowledgeable about the risk of excessive acoustic energy in the body, particularly in the case where a great amount of fluid is present in the scanning area.

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)

**510(k) Summary**

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**

|   |   |
|---|---|
| <u>Submitted by:</u><br>SuperSonic Imagine, S.A.<br>Zac de l'Enfant 135 Rue Émilien Gautier<br>13290 Aix-En-Provence<br>FRANCE<br>Telephone: +33(4) 42 99 24 24<br>E-mail: contactsFR@supersonicimagine.com | <u>Distributed by:</u><br>Hologic Headquarters.<br>250 Campus Drive<br>Marlborough, MA 01752<br>USA<br>Tel: +1.508.263.2900<br>Fax: +1.781.280.0668<br>E-mail: info@hologic.com |
|---|---|

Corresponding Official:

Shalyna BANSROPUN,  
 Quality and Regulatory Affairs Manager  
 Telephone: +33(6) 77 23 08 42

Date: Sept-22-2022

**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 / SUPERSONIC MACH Ultrasound Diagnostic Systems
- AIXPLORER® MACH 30 / SUPERSONIC MACH30,
- AIXPLORER® MACH 20 / SUPERSONIC MACH 20,
- SUPERSONIC MACH 40

Classification: Class II

| <b>Classification Name:</b>              | <b>21 CFR Section</b> | <b>Product Code</b> |
|--|-----------------------|---------------------|
| 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 (K203645), cleared on 06/29/2021 |
| Reference devices        | AIXPLORER® MACH range Ultrasound Imaging System (K202455), cleared on 12/29/2020 |
|                          | 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 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 Hologic SuperSonic Imagine 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 Hologic SuperSonic SUPERSONIC MACH range 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.

Modes of operation include: B-mode [2D ; 3D ; Panoramic Imaging; Spatial Compounding ], M-mode , Doppler [Continuous Wave (CW); Pulsed Wave (PW); Color and Power Doppler (Color Flow Imaging), Color Doppler (Angio PL.U.S) ], Strain Elastography, Tissue Harmonic Imaging, Contrast Enhanced Ultrasound Imaging (CEUS); ShearWave Elastography (SWE); ShearWave dispersion Viscosity (Vi PLUS); Combination Modes [ (B/Color Flow) ; (B/SWE), ( B/PW), (B/PW/Color Flow); (B/ M-mode); (B/Color flow/SWE); (B/CW) ; (B/M-mode/Color flow); (B/Strain Elastography/SWE)].”

In addition, the Hologic SuperSonic Imagine SUPERSONIC 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 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 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.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to use or direct the use of the device. This device is intended for use in hospital environment or physician's office.

This system should only be used by trained Health Care Professionals (HCP) who are knowledgeable about the risk of excessive acoustic energy in the body, particularly in the case where a great amount of fluid is present in the scanning area.

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

|                            | SuperSonic Imagine   | SuperSonic Imagine   | Canon Medical System   | Mindray medical International  | SuperSonic Imagine                           |
|----------------------------|--|--|--|--|--|
|                            | Aixplorer MACH range sw V3<br>(predicate)  | Aixplorer MACH range sw V2.1<br>(Reference)  | Aplio i900, i800 and i700 V2.0<br>(Reference)                          | Resona 7<br>(Reference)  | AIXPLORER® MACH / SUPERONIC MACH range sw V4 |
| <b>510(k) Number</b>       | K203645  | K202455  | K173090  | K171233  | K222191                                      |
| <b>Classification Name</b> | Ultrasonic Pulsed Doppler Imaging System (892.1550)<br>Ultrasonic Pulsed Echo Imaging System (892.1560)<br>Diagnostic Ultrasound Transducer (892.1570) | Ultrasonic Pulsed Doppler Imaging System (892.1550)<br>Ultrasonic Pulsed Echo Imaging System (892.1560)<br>Diagnostic Ultrasound Transducer (892.1570) | Identical  | Identical  | Identical                                    |
| <b>Class</b>               | Class II   | Class II   | Identical  | Identical  | Identical                                    |
| <b>Intended Use</b>        | Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body   | 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 K203645                         |

|                           | SuperSonic Imagine   | SuperSonic Imagine   | Canon Medical System  | Mindray medical International  | SuperSonic Imagine   |
|---------------------------|--|--|---|--|--|
| <b>Indication for Use</b> | <p>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.</p> <p>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.</p> <p>In addition, the SuperSonic Imagine AIXPLORER® MACH/ SUPERSONIC MACH ultrasound diagnostic systems and associated transducers are intended for:</p> | <p>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.</p> <p>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.</p> <p>In addition, the SuperSonic Imagine AIXPLORER® MACH/ SUPERSONIC MACH ultrasound diagnostic systems and associated transducers are intended for:</p> | <p>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 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</p> | <p>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), neonatal cephalic, adult cephalic, trans-rectal, transvaginal, muscul o-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, transesoph. (cardiac), peripheral vessel and urology exams.</p> | <p>Identical to K203645</p> <p>Additional information for clarification on “Operator qualification and device use settings” and “mode of operation”.</p> |



|  | SuperSonic Imagine   | SuperSonic Imagine   | Canon Medical System   | Mindray medical International | SuperSonic Imagine |
|--|--|--|--|-------------------------------|--------------------|
|  | <ul style="list-style-type: none"> <li>-Measurements of abdominal anatomical structures,</li> <li>- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,</li> <li>- Measurements of brightness ratio between liver and kidney,</li> <li>- Visualization of abdominal vascularization, microvascularization and perfusion,</li> <li>- Quantification of abdominal vascularization and perfusion.</li> </ul> <p>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.</p> | <ul style="list-style-type: none"> <li>-Measurements of abdominal anatomical structures,</li> <li>- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,</li> <li>- Measurements of brightness ratio between liver and kidney,</li> <li>- Visualization of abdominal vascularization, microvascularization and perfusion,</li> <li>- Quantification of abdominal vascularization and perfusion.</li> </ul> <p>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.</p> | <p>vascular, transoesophageal, musculoskeletal (both conventional and supercificial) and laparoscopic.</p> |                               |                    |

|  | SuperSonic Imagine  | SuperSonic Imagine | Canon Medical System | Mindray medical International | SuperSonic Imagine |
|--|---|--------------------|----------------------|-------------------------------|--------------------|
|  | <p>Furthermore, the SuperSonic Imagine MACH ultrasound diagnostic systems and associated transducers are intended for:</p> <ul style="list-style-type: none"> <li>- Measurements of breast anatomical structures</li> <li>- Measurements of broad band shear waves speed and tissue stiffness in internal structures of the breast</li> <li>- Visualization of breast structures and micro-vascularization</li> <li>- Visualization of breast masses morphology using shearwave elastography and micro-vascularization 2D mapping</li> </ul> <p>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.</p> |                    |                      |                               |                    |

|                              | SuperSonic Imagine   | SuperSonic Imagine   | Canon Medical System | Mindray medical International | SuperSonic Imagine   |
|------------------------------|--|--|----------------------|-------------------------------|----------------------|
| <b>General Description</b>   | General purpose, mobile, software controlled diagnostic ultrasound system. To acquire ultrasound data and to display the data in various modes of operation.                             | 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...). | 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            |
| <b>Clinical Applications</b> | Abdominal (liver, kidney, spleen)  | Abdominal (liver, kidney, spleen)  | Identical            | Identical                     | Identical            |
|                              | Small organs (*)   | Small organs (*)   | Identical            | Identical                     | Identical            |
|                              | Musculoskeletal  | Musculoskeletal  | Identical            | Identical                     | Identical            |
|                              | Fetal  | Fetal  | Identical            | Identical                     | Identical            |
|                              | GYN  | GYN  | Identical            | Identical                     | Identical            |
|                              | Cardiac (non invasive)   | Cardiac (non invasive)   | Identical            | Identical                     | Identical to K203645 |
|                              | Adult and neonatal cephalic  | Adult and neonatal cephalic  | Identical            | Identical                     | Identical            |
|                              | Pediatric  | Pediatric  | Identical            | Identical                     | Identical            |
|                              | Urology  | Urology  | Identical            | Identical                     | Identical            |

|                      | SuperSonic Imagine             | SuperSonic Imagine             | Canon Medical System | Mindray medical International | SuperSonic Imagine   |
|----------------------|--------------------------------|--------------------------------|----------------------|-------------------------------|----------------------|
|                      | Vascular                       | Vascular                       | Identical            | Identical                     | Identical            |
|                      | Peripheral vascular            | Peripheral vascular            | Identical            | Identical                     | Identical            |
|                      | Trans-rectal                   | Trans-rectal                   | Identical            | Identical                     | Identical            |
|                      | Trans-vaginal                  | Trans-vaginal                  | Identical            | Identical                     | Identical            |
| <b>Imaging modes</b> |                                |                                |                      |                               |                      |
| <b>Conventional</b>  | B-Mode (Harmonic, Fundamental) | B-Mode (Harmonic, Fundamental) | Identical            | Identical                     | Identical            |
|                      | M-Mode                         | M-Mode                         | Identical            | Identical                     | Identical            |
|                      | PW                             | PW                             | Identical            | Identical                     | Identical            |
|                      | CW                             | CW                             | Identical            | Identical                     | Identical            |
|                      | Color Doppler                  | Color Doppler                  | Identical            | Identical                     | Identical            |
|                      | Amplitude Doppler              | Amplitude Doppler              | Identical            | Identical                     | Identical            |
|                      | Microvascular (Angio PL.U.S)   | Microvascular (Angio PL.U.S)   | --- (**)             | ---                           | Identical to K203645 |
| <b>Other</b>         | Spatial compounding, Panoramic | Spatial compounding, Panoramic | Identical            | Identical                     | Identical            |
|                      | Contrast                       | Contrast                       | Identical            | Identical                     | Identical to K202455 |
|                      | Combination of modes           | Combination of modes           | Identical            | Identical                     | Identical            |
|                      | ShearWave Elastography         | ShearWave Elastography         | Identical            | Identical                     | Identical            |
|                      | Strain Elastography            | Strain Elastography            | Identical            | Identical                     | Identical            |

|  | SuperSonic Imagine   | SuperSonic Imagine   | Canon Medical System | Mindray medical International | SuperSonic Imagine   |
|--|--|--|----------------------|-------------------------------|--|
| <b>Design</b>                                |  |  |                      |                               |  |
| <b>Cart</b>                                  | Mobile cart based product with control panel and monitor         | Mobile cart based product with control panel and monitor         | Identical            | Identical                     | Identical  |
| <b>Controls</b>                              | Typical ultrasound imaging controls (gain, depth mode select...) | Typical ultrasound imaging controls (gain, depth mode select...) | Identical            | Identical                     | Identical  |
| <b>Biopsy guide</b>                          | Available  | Available  | Identical            | Identical                     | Identical  |
| <b>Track</b>                                 | Track 3 (Acoustic Output Display)                                | Track 3 (Acoustic Output Display)                                | Identical            | Identical                     | Identical  |
| <b>Patient Contact Materials</b>             | Yes, per ISO 10993-1   | Yes, per ISO 10993-1   | Identical            | Identical                     | Identical  |
| <b>Acoustic Output within FDA guidelines</b> | Yes, as per NEMA UD-3  | Yes, as per NEMA UD-3  | Identical            | Identical                     | Identical  |
|  |  |  |                      |                               |  |
| <b>Software Operation System</b>             | Linux (Debian 9)   | Linux (Debian 9)   | Windows              | Windows                       | Linux (Debian 11)  |
| <b>Image Review</b>                          | Yes  | Yes  | Identical            | Identical                     | Improvement of image quality presets (Angio, Abdo & Thyroid, MSK, Ultrafast Doppler Vascular). |
| <b>Measurement Package</b>                   | Yes  | Yes  | Identical            | Identical                     | Identical  |
| <b>Calculation Package</b>                   | Yes  | Yes  | Identical            | Identical                     | Identical  |

|                            | SuperSonic Imagine                            | SuperSonic Imagine                            | Canon Medical System | Mindray medical International | SuperSonic Imagine                                |
|----------------------------|---|---|----------------------|-------------------------------|---|
| <b>Automated Protocols</b> | No  | No  | Yes                  | Yes                           | Inclusion of Optional Automated Protocols feature |
| <b>Report</b>              | Yes   | Yes   | Identical            | Identical                     | Identical   |
| <b>General Safety</b>      | Conforms to IEC60601-1, 60601-1-2, 60601-2-37 | Conforms to IEC60601-1, 60601-1-2, 60601-2-37 | Identical            | Identical                     | Identical   |
|                            |   |   |                      |                               |   |
| <b>Labeling</b>            | Conforms to 21 CFR Part 801                   | 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.

| <b>Reference Standard</b> | <b>Tests Performed</b>  |
|---------------------------|---|
| 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 / 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.