



September 20, 2024

SuperSonic Imagine  
% Charlotte Turc  
Official Correspondent  
Zac de l'Enfant 135 Rue Émilien Gautier  
Aix-En-Provence, 13290  
FRANCE

Re: K242223

Trade/Device Name: SuperSonic® HepaVu™  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic Pulsed Doppler Imaging System  
Regulatory Class: Class II  
Product Code: IYN, IYO, ITX  
Dated: July 29, 2024  
Received: September 4, 2024

Dear Charlotte Turc:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

**Marjan Nabili -S** for

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)  
K242223

Device Name  
SuperSonic® HepaVu™

### Indications for Use (Describe)

The SuperSonic Imagine® SuperSonic® HepaVu™ ultrasound diagnostic system 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® SuperSonic® HepaVu™ ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal for Adult and Pediatric.

Modes of operation include: B-mode [2D ; Panoramic Imaging; Spatial Compounding], M-mode, Doppler [Pulsed Wave (PW); Color and Power Doppler (Color Flow Imaging), Color Doppler (Angio PL.U.S)], 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/M-mode/Color flow)].

In addition, the SuperSonic Imagine® SuperSonic® HepaVu™ ultrasound diagnostic systems and associated transducers are intended for:

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

The shear wave speed, ultrasound attenuation coefficient, backscattering coefficient, 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.

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<sup>1</sup>. 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.

<sup>1</sup> Information delivered by the device must be used by a licensed physician qualified to establish a diagnosis.

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.**

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## 510(K) Summary

**K242223**

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

|                                           |
|-------------------------------------------|
| SuperSonic Imagine, S.A.                  |
| Zac de l'Enfant 135 Rue Émilien Gautier   |
| 13290 Aix-En-Provence                     |
| FRANCE                                    |
| Telephone: +33(4) 42 99 24 24             |
| E-mail : contactsFR@supersonicimagine.com |

#### Primary Contact:

Shalyna BANSROPUN,  
 Quality and Regulatory Affairs Manager  
 Telephone: +33(4) 42 99 24 24

Date: September-19-2024

### 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: SuperSonic® HepaVu™

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 Device

AIXPLORER® / SUPERSONIC® MACH range Ultrasound Imaging System (K222191), cleared on 10/28/2022

## 4. Description of Device

The SuperSonic Imagine® SuperSonic® HepaVu™ systems are cart based ultrasound imaging systems used to perform non-invasive diagnostic hepatology purpose ultrasound imaging studies.

The system contains a scan converter and can be coupled to a variety of linear and curved transducers to produce images, which are displayed on a LCD monitor. An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles.

The system also allows the user to perform measurements, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report. The system functions in a manner identical to the predicate devices and transducers for the imaging modes: B-Mode (harmonic or fundamental), M-mode, Color Flow (and sub-modes as CFI-ColorFlow Imaging, CPI-ColorPower Imaging- also called Amplitude Doppler, dCPI-directional Color Power Imaging and Angio PL.U.S), Pulsed Wave Doppler, 3D imaging, CEUS-Contrast Enhanced Ultrasound Imaging and for ShearWave™ elastography and Strain Elastography.

The principle software change with respect to the MACH software version is related to the introduction of the following feature:

- **Backscattering coefficient (BSc):** The backscattering coefficient characterizes the ability of a tissue to reflect incoming ultrasound wave back to the direction from which they came.  
 Local measurement of the backscattering is expressed in db/cm.str over a range of values (from -38 db/cm.str to -24 db/cm.str).  
 Bsc PLUS mode is available for all Abdominal presets on C6-1X and C9-2X transducers.

## 5. Indications for Use

The SuperSonic Imagine® SuperSonic® HepaVu™ ultrasound diagnostic system 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® SuperSonic® HepaVu™ ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal for Adult and Pediatric.

Modes of operation include: B-mode [2D ; Panoramic Imaging; Spatial Compounding], M-mode, Doppler [Pulsed Wave (PW); Color and Power Doppler (Color Flow Imaging), Color Doppler (Angio PL.U.S)], 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/M-mode/Color flow)].

In addition, the SuperSonic Imagine® SuperSonic® HepaVu™ 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 shear wave speed, ultrasound attenuation coefficient, backscattering coefficient, 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.

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<sup>1</sup>. 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.

<sup>1</sup> Information delivered by the device must be used by a licensed physician qualified to establish a diagnosis.

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

|                            | NEW DEVICE<br><b>SuperSonic® HepaVu™</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | PREDICATE DEVICE<br><b>AIXPLORER® MACH / SUPERSONIC® MACH range</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Discussion                               |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>510(k) Number</b>       | Unknown                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | K222191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | -                                        |
| <b>Classification Name</b> | <p>Ultrasonic Pulsed Doppler Imaging System (892.1550)</p> <p>Ultrasonic Pulsed Echo Imaging System (892.1560)</p> <p>Diagnostic Ultrasound Transducer (892.1570)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>Ultrasonic Pulsed Doppler Imaging System (892.1550)</p> <p>Ultrasonic Pulsed Echo Imaging System (892.1560)</p> <p>Diagnostic Ultrasound Transducer (892.1570)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Identical                                |
| <b>Class</b>               | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Identical                                |
| <b>Product Code</b>        | IYN, IYO, ITX                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | IYN, IYO, ITX                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Identical                                |
| <b>Indications for use</b> | <p>The SuperSonic Imagine® SuperSonic® HepaVu™ ultrasound diagnostic system 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® SuperSonic® HepaVu™ ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal for Adult and Pediatric.</p> <p>Modes of operation include: B-mode [2D ; Panoramic Imaging; Spatial Compounding], M-mode, Doppler [Pulsed Wave (PW); Color and Power Doppler (Color Flow Imaging), Color Doppler (Angio PL.U.S)], 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/M-mode/Color flow)].</p> <p>In addition, the SuperSonic Imagine® SuperSonic® HepaVu™ range ultrasound diagnostic systems and associated transducers are intended for:</p> <p>Measurements of abdominal anatomical structures,</p> <p>Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,</p> | <p>The 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.</p> <p>The SuperSonic Imagine® SuperSonic® MACH Range ultrasound 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, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Transvaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac.</p> <p>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)].</p> <p>In addition, the SuperSonic Imagine® SuperSonic® MACH Range ultrasound diagnostic systems and associated transducers are intended for:</p> <p>Measurements of abdominal anatomical structures,</p> | Identical: adapted to liver applications |

|                            | NEW DEVICE<br><b>SuperSonic® HepaVu™</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | PREDICATE DEVICE<br><b>AIXPLORER® MACH / SUPERSONIC® MACH range</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Discussion |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
|                            | <p>Measurements of brightness ratio between liver and kidney,<br/>Visualization of abdominal vascularization, microvascularization and perfusion,<br/>Quantification of abdominal vascularization and perfusion</p> <p>The shear wave speed, ultrasound attenuation coefficient, backscattering coefficient, 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>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<sup>1</sup>. 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.</p> <p><i>1 Information delivered by the device must be used by a licensed physician qualified to establish a diagnosis.</i></p> | <p>Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,<br/>Measurements of brightness ratio between liver and kidney,<br/>Visualization of abdominal vascularization, microvascularization and perfusion,<br/>Quantification of abdominal vascularization and perfusion</p> <p>The shear wave 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>Furthermore, the SuperSonic® MACH ultrasound diagnostic systems and associated transducers are intended for:</p> <p>Measurement of breast anatomical structures<br/>Measurements of broad band shear waves speed and tissue stiffness in internal structures of the breast<br/>Visualization of breast structures and micro-vascularization<br/>Visualization of breast masses morphology using shearwave elastography and mmicro-vascularization 2D mapping.</p> <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 improved the diagnostic accuracy of ultrasound.</p> <p>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.</p> <p><i>1 Information delivered by the device must be used by a licensed physician qualified to establish a diagnosis.</i></p> |            |
| <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  |

|                              | NEW DEVICE<br>SuperSonic® HepaVu™                                                                                                                                                        | PREDICATE DEVICE<br>AIXPLORER® MACH / SUPERSONIC® MACH range                                                                                                                             | Discussion                              |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
|                              | 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                               |
| <b>Clinical Applications</b> | Abdominal (liver, kidney, spleen)                                                                                                                                                        | Abdominal (liver, kidney, spleen)                                                                                                                                                        | Identical                               |
|                              | -                                                                                                                                                                                        | Small organs (Breast, Thyroid, Testicle, etc)                                                                                                                                            | N/A                                     |
|                              | -                                                                                                                                                                                        | Musculoskeletal                                                                                                                                                                          | N/A                                     |
|                              | -                                                                                                                                                                                        | Fetal                                                                                                                                                                                    | N/A                                     |
|                              | -                                                                                                                                                                                        | GYN                                                                                                                                                                                      | N/A                                     |
|                              | -                                                                                                                                                                                        | Cardiac (non invasive)                                                                                                                                                                   | N/A                                     |
|                              | -                                                                                                                                                                                        | Adult and neonatal cephalic                                                                                                                                                              | N/A                                     |
|                              | Pediatric                                                                                                                                                                                | Pediatric                                                                                                                                                                                | Identical use for pediatric (Abdominal) |
|                              | -                                                                                                                                                                                        | Urology                                                                                                                                                                                  | N/A                                     |
|                              | -                                                                                                                                                                                        | Vascular                                                                                                                                                                                 | N/A                                     |
|                              | -                                                                                                                                                                                        | Peripheral vascular                                                                                                                                                                      | N/A                                     |
|                              | -                                                                                                                                                                                        | Trans-rectal                                                                                                                                                                             | N/A                                     |
|                              | -                                                                                                                                                                                        | Trans-vaginal                                                                                                                                                                            | N/A                                     |
|                              |                                                                                                                                                                                          |                                                                                                                                                                                          |                                         |
| <b>Imaging modes</b>         |                                                                                                                                                                                          |                                                                                                                                                                                          |                                         |
| <b>Conventional</b>          | B-Mode (Harmonic, Fundamental)                                                                                                                                                           | B-Mode (Harmonic, Fundamental)                                                                                                                                                           | Identical                               |
|                              | M-Mode                                                                                                                                                                                   | M-Mode                                                                                                                                                                                   | Identical                               |
|                              | PW                                                                                                                                                                                       | PW                                                                                                                                                                                       | Identical                               |
|                              | -                                                                                                                                                                                        | CW                                                                                                                                                                                       | N/A                                     |
|                              | Color Doppler                                                                                                                                                                            | Color Doppler                                                                                                                                                                            | Identical                               |
|                              | Amplitude Doppler                                                                                                                                                                        | Amplitude Doppler                                                                                                                                                                        | Identical                               |
|                              | Microvascular (Angio PL.U.S)                                                                                                                                                             | Microvascular (Angio PL.U.S)                                                                                                                                                             | Identical                               |
| <b>Other</b>                 | Spatial compounding, Panoramic                                                                                                                                                           | Spatial compounding, Panoramic                                                                                                                                                           | Identical                               |
|                              | Contrast                                                                                                                                                                                 | Contrast                                                                                                                                                                                 | Identical                               |
|                              | Combination of modes                                                                                                                                                                     | Combination of modes                                                                                                                                                                     | Identical                               |
|                              | ShearWave Elastography                                                                                                                                                                   | ShearWave Elastography                                                                                                                                                                   | Identical                               |
|                              | -                                                                                                                                                                                        | Strain Elastography                                                                                                                                                                      | N/A                                     |
|                              | Attenuation (Att PLUS)                                                                                                                                                                   | Attenuation (Att PLUS)                                                                                                                                                                   | Identical                               |
|                              | Sound Speed Plane wave (SSp PLUS)                                                                                                                                                        | Sound Speed Plane wave (SSp PLUS)                                                                                                                                                        | Identical                               |
|                              | Backscattering (Bsc plus)                                                                                                                                                                | -                                                                                                                                                                                        | New                                     |
| <b>Design</b>                |                                                                                                                                                                                          |                                                                                                                                                                                          |                                         |

|                                              | NEW DEVICE<br>SuperSonic® HepaVu™                                                                          | PREDICATE DEVICE<br>AIXPLORER® MACH / SUPERSONIC® MACH range                                                                                                                                            | Discussion                                                                             |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| <b>Cart</b>                                  | Mobile cart based product with control panel and monitor                                                   | Mobile cart based product with control panel and monitor                                                                                                                                                | Identical                                                                              |
| <b>Controls</b>                              | Typical ultrasound imaging controls (gain, depth mode select...)                                           | Typical ultrasound imaging controls (gain, depth mode select...)                                                                                                                                        | Identical                                                                              |
| <b>Biopsy guides</b>                         | Available                                                                                                  | Available                                                                                                                                                                                               | Identical                                                                              |
| <b>Track</b>                                 | Track 3 (Acoustic Output Display)                                                                          | Track 3 (Acoustic Output Display)                                                                                                                                                                       | Identical                                                                              |
| <b>Patient Contact Materials</b>             | Yes, per ISO 10993-1 :2018                                                                                 | Yes, per ISO 10993-1 :2018                                                                                                                                                                              | Identical                                                                              |
| <b>Acoustic Output within FDA guidelines</b> | Yes, as per NEMA UD-3                                                                                      | Yes, as per NEMA UD-3                                                                                                                                                                                   | Identical                                                                              |
| <b>General Safety</b>                        | Conform to IEC60601-1:2020, 60601-1-2:2020, 60601-2-37:2015                                                | Conform to IEC60601-1:2020, 60601-1-2:2020, 60601-2-37:2015                                                                                                                                             | Identical                                                                              |
| <b>Accessoires</b>                           |                                                                                                            |                                                                                                                                                                                                         |                                                                                        |
| <b>Probes</b>                                | -<br>L10-2<br>C6-1X<br>C9-2X<br>-<br>-<br>-<br>-<br>-                                                      | L18-5<br>L10-2<br>C6-1X<br>C9-2X<br>LV16-5<br>LH20-6<br>P5-1X<br>E12-3<br>MC12-3                                                                                                                        | Identical with reduction of the number of probes in accordance with the HepaVu™ scope. |
| <b>Cleaning &amp; Disinfectants</b>          | Yes                                                                                                        | Yes                                                                                                                                                                                                     | Identical                                                                              |
| <b>Probe sheaths</b>                         | C6-1X & C9-2X probes<br>610-637<br>610-1000<br>610-542<br>610-362<br><br>L10-2 probe<br>610-323<br>610-001 | C6-1X & C9-2X probes<br>610-637<br>610-1000<br>610-542<br>610-362<br><br>L10-2 probe<br>610-323<br>610-001                                                                                              | Identical with reduction of the number of probes in accordance with the HepaVu™ scope. |
| <b>Gel</b>                                   | Yes                                                                                                        | Yes                                                                                                                                                                                                     | Identical                                                                              |
| <b>Biopsy Guides</b>                         | C6-1X probe<br>672-002 by Clvco<br>610-901 by Clvco<br><br>C9-2X probe<br>653-005 by Clvco                 | L18-5 probe<br>672-001 by Clvco<br><br>C6-1X probe<br>672-002 by Clvco<br>610-901 by Clvco<br><br>E12-3 probe<br>657-014 by Clvco<br>610-666 by Clvco<br>610-1275 by Clvco<br>Aquamarine #9000 by Clvco | Identical with reduction of the number of probes in accordance with the HepaVu™ scope. |

|                        | <b>NEW DEVICE</b><br><b>SuperSonic® HepaVu™</b> | <b>PREDICATE DEVICE</b><br><b>AIXPLORER® MACH / SUPERSONIC® MACH range</b> | <b>Discussion</b> |
|------------------------|-------------------------------------------------|----------------------------------------------------------------------------|-------------------|
| <b>Gel warmer</b>      | Yes                                             | Yes                                                                        | Identical         |
| <b>Footswitch</b>      | Yes                                             | Yes                                                                        | Identical         |
| <b>DICOM</b>           | Yes                                             | Yes                                                                        | Identical         |
| <b>Barcode Scanner</b> | Yes                                             | Yes                                                                        | Identical         |
| <b>ECG</b>             | Yes                                             | Yes                                                                        | Identical         |

## 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 has been conducted per the following standards, as per the below table :

| <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 SuperSonic® HepaVu™ System performs in accordance with 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. No clinical tests have been performed on SuperSonic® HepaVu™ System.

## **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 device.

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