DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2017

Supersonic Imagine
% Mr. Laurence Hermitte
Quality & Regulatory Affairs Director
Les Jardins de la Duranne
510, rue Rene Descartes - Bat E&F
Aix-en-Provence Cedex 13857
FRANCE

Re: K171105
Trade/Device Name: AIXPLORER® & AIXPLORER® Ultimate Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 14, 2017
Received: April 17, 2017

Dear Mr. Hermitte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171105

Device Name
AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems

Indications for Use *(Describe)*
The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, Doppler fluid flow analysis of the human body.
The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems are indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal, Neonatal/Adult Cephalic, and Non-invasive Cardiac.
The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, Intraoperative, GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal, Neonatal/Adult Cephalic, Fetal/Obstetrics, Cardiac).

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

1) Submitter's name, address, telephone number, contact person

Submitted by:
SuperSonic Imagine, S.A.
Les Jardins de la Duranne – Bât. E & F
510, rue René Descartes
13857 Aix-en-Provence Cedex
France
Telephone: +33 442 99 24 24

Distributed by:
SuperSonic Imagine, Inc.
Weston
North America
Telephone: +1(954) 660 3528

Corresponding Official:

Jacques Souquet
Chief Innovation Officer
Telephone: +33 442 99 24 35

Date: 2017.03.31

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: Diagnostic Ultrasound System with Accessories
Proprietary Name: AIXPLORER® & AIXPLORER® Ultimate Ultrasound Diagnostic Systems

Classification:

Regulatory Class: II

Classification Name:	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Substantially Equivalent/Predicate Devices

Toshiba System, Diagnostic Ultrasound (K141459), cleared on 10/28/2014
AIXPLORER® Ultrasound Imaging System (K161999), cleared on 11/16/2016

4) Description of Device

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate are a cart based ultrasound imaging system 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, and Angio PL.U.S), Pulsed Wave Doppler, 3D imaging and for ShearWave™ elastography.

5) Intended Use

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, Doppler fluid flow analysis of the human body.

The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems are indicated for use in the following applications: 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.

The systems also provide the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, Intraoperative, GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal, Neonatal/Adult Cephalic, Fetal/Obstetrics, Cardiac).

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

	Toshiba	**SuperSonic Imagine**	**New devices**
	Toshiba Device **(predicate)**	**SuperSonic Imagine AIXPLORER®** **(predicate)**	**SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate** **(New devices)**
510(k) Number	K141459	K161999	Unassigned
Classification Name	Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) Diagnostic Ultrasound Transducer (892.1570)	Identical	Identical
Class	Class II	Identical	Identical

	Toshiba	SuperSonic Imagine	New devices
Intended Use	Identical	Identical	Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body
General Description	General purpose, mobile, software controlled diagnostic ultrasound system. To acquire ultrasound data and to display the data in various modes of operation.	Identical	Identical
	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
	Includes physical knobs and buttons of the main control panel and the user interface which consists of a Touch Panel, to access additional less-frequently-used controls, and the Alphanumeric Keyboard to enter patient data and other text.	Identical	Identical
SWE Dynamic Range	---	Adjustable range capability and numeric display with scale	Identical to K161999
Clinical Applications	Abdominal,	Identical	Identical
	Small Organs*	Identical	Identical
	Musculoskeletal	Identical	Identical
	Superficial Musculoskeletal	Identical	Identical
	Fetal	Identical	Identical
	GYN	Identical	Identical

	Toshiba	SuperSonic Imagine	New devices
	Cardiac	Identical	Identical
	Adult and neonatal cephalic	Identical	Identical
	Pediatric	Identical	Identical
	Urology	Identical	Identical
	Vascular	Identical	Identical
	Peripheral Vascular	Identical	Identical
	Intra-operative	Identical	Identical
	Trans-rectal	Identical	Identical
	Trans-vaginal	Identical	Identical
Imaging Modes			
Conventional	B-mode (Harmonic/Fundamental)	Identical	Identical
	M-mode,	Identical	Identical
	PW,	Identical	Identical
	CW (continuous Wave),	---	---
	Color Doppler,	Identical	Identical
	Amplitude Doppler (CPI),	Identical	Identical
	Microvascular SMI	Identical (called Angio PL.U.S)	Identical (called Angio PL.U.S)
Other	Spatial Compounding, Panoramic,	Identical	Identical
	Contrast	Identical	Identical
	Combination of modes	Identical	Identical
Design			
Cart	Mobile cart-based product with control panel and monitor	Identical	Identical
Controls	Typical ultrasound imaging controls including power output, gain, depth, focus, freeze, PRF, mode select	Identical	Identical

	Toshiba	SuperSonic Imagine	New devices
Transducers			
Transducer types	Linear Array Curved Array Phased Array Motorized Linear Probe Microconvex probe	Identical Identical Identical Identical Identical	Identical Identical Identical Identical Identical
Biopsy guide	Yes BEAM	Yes ---	Yes Identical (called Needle PL.U.S.)
Track	Track 3 (Acoustic Output Display)	Identical	Identical
Patient Contact Materials	Yes, per ISO-10993-1	Identical	Identical
Acoustic Output within FDA guidelines	Yes, as per NEMA UD-3	Identical	Identical
Image Review	Yes	Identical	Identical
Measurement Package	Yes	Identical	Identical
Calculation Package	Yes	Identical	Identical
Report	Yes	Identical	Identical
General Safety	Conforms to IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37	Identical	Identical
Labeling	Conforms to 21 CFR Part 801	Identical	Identical
General Description	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
General Description SWE Dynamic Range	Includes physical knobs and buttons of the main control panel and the user interface which consists of a Touch	Identical	Identical

	Toshiba	SuperSonic Imagine	New devices
	Panel, to access additional less-frequently-used controls, and the Alphanumeric Keyboard to enter patient data and other text.		
	---	Adjustable range capability and numeric display with scale	Identical to K161999

Note:
*: Breast, Thyroid, Testicle, etc

7) A brief discussion of the non clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Non-clinical testing was conducted per the following standards to support a determination of substantial equivalence to the predicate devices.

Reference Standard	Tests Performed
IEC 60601-1 3.1 Edition	All applicable electrical, basic safety and essential performance tests.
IEC 60601-1-2 3rd Edition	All applicable testing pertaining to electromagnetic compatibility.
IEC 60601-2-37 2nd Edition	All applicable testing pertaining to the particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
NEMA UD 2 (Rev. 3)	All tests applicable in order to demonstrate compliance with the “Accoustic Output Measurement Standard for Diagnostic Ultrasound Equipment”.
NEMA UD 3 (Rev. 2)	All tests applicable in order to demonstrate compliance with the “Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment”.
ISO 10993-1	Applicable biocompatibility tests per FDA 510(k) Memorandum - #G95-1 – per the appropriate device category.

The above testing confirmed that the Aixplorer® System performs 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® and Aixplorer® Ultimate 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

Clinical data is not required as the Aixplorer® and Aixplorer® Ultimate Systems use the same technology and principles as predicate devices.

9) Conclusion

The manufacturer and the design and development of the submission device comply with 21 CFR Part 820 and ISO 13485 (2003) Quality Standards. The submission device, designed to comply with applicable safety standards, is tested during manufacturing process to ensure compliance with these standards. Consequently, according tests performed, the opinion of SuperSonic Imagine is the submission device is as safe and effective as the predicate devices cited in item 3.