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

AUG 12 2009

Submitted by:
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Aurelie Gruener
Regulatory Affairs Manager
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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®

Classification:

Regulatory Class: II
Review Category: Tier 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

Siemens Acuson S2000™ Ultrasound System (K072786), 11/13/2007
Philips Ultrasound Boris Platform Diagnostic Ultrasound System (K030455), 3/13/2003

4) Description of Device

The SuperSonic Imagine AIXPLORER® system is 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 linear array transducer 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 and associated calculations, 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 equivalent to the predicate devices (see section 4.5.2 for predicate devices) and transducers for the imaging modes: B-Mode imaging, Color Flow imaging, Color Power imaging, Pulsed Wave Doppler, and Elastography Imaging.

5) Intended Use

The SuperSonic Imagine AIXPLORER® ultrasound system and transducer are intended for general purpose pulse echo ultrasound imaging and Doppler fluid flow analysis of the human body.

6) Indication for Use

The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal and Peripheral Vascular.

The system also provides the ability to measure anatomical structures (abdominal, small organs, musculoskeletal, superficial musculoskeletal and peripheral vascular).

7) Safety Considerations

As a Track 3 ultrasound device, the SuperSonic Imagine AIXPLORER® ultrasound system is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (1992)" published by the National Electrical Manufacturers Association as UD -3. With respect to limits on acoustic outputs, the SuperSonic Imagine AIXPLORER® ultrasound system complies with the FDA guideline limits set in the September 30, 1997, 510(k) diagnostic ultrasound guidance.
With regard to general safety, the SuperSonic Imagine AIXPLORER® ultrasound system scanner is designed to comply with IEC 60101 -1 (2005) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, and IEC 60601 - 2-37 (2007): Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The device's acoustic output limits are:

Mechanical Index	1.9 (Maximum)
TIS/TIB	0.1 – 4.0 (Range)
ISPTA (d)	720 mW/cm2
ISPPA (d)	0 – 700 W/cm2

The limits are the same as predicate Track 3 devices. These considerations apply to all modes the system offers.

8) Comparison to Predicate Devices

The SuperSonic Imagine AIXPLORER® system and transducer are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The systems have the same clinical indications for use.
- The systems have the same B-Mode (grayscale imaging) and Doppler capabilities.
- The systems have similar capability in terms of harmonic imaging, spatial compound imaging, elastography imaging and other image post-processing features to improve the image quality and aid in clinical evaluation and diagnosis.
- The transducers are similar in materials, manufacture and clinical capability.

- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The systems have been found to be manufactured in compliance with approved electrical and physical safety standards.

9) Conclusion

The documentation provided demonstrates that:

1) The system and transducer are substantially equivalent to the predicate devices.
2) There are no new questions of safety and effectiveness concerning the SuperSonic Imagine AIXPLORER® ultrasound system and transducer.
3) The ultrasound device has been scientifically evaluated and has been demonstrated to be at least as safe and effective as the predicate devices cited in item 3.

   The system's acoustic power levels are below the applicable FDA limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Jacques Souquet, CEO
SuperSonic Imagine, Inc.
LES Jardin De La Duranne-Bat. E & F
510 Rue Rene Descartes
13857 Aix-en-Provence Cedex
FRANCE

AUG 12 2009

Re: K091970
Trade/Device Name: AIXPLORER® Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 30, 2009
Received: July 1, 2009

Dear Mr. Souquet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the AIXPLORER® Ultrasound System, as described in your premarket notification:

Transducer Model Number

SL 15-4

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 796-5506. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K091970

Device Name: AIXPLORER® Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Indications for Use:
The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal and Peripheral Vascular.

The system also provides the abilily to measure anatomical structures (abdominal, small organs, musculoskeletal, superficial musculoskeletal and peripheral vascular).

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091970

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K091970
Device Name: **AIXPLORER® Ultrasound System**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Notes
Ophthalmic										
Fetal										
Abdominal		N		N		N	N		1, 2	3,4,5,6
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Breast, Thyroid, Testicle, Prostate)		N		N		N	N		1, 2	3,4,5,6
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N		N		N	N		1, 2	3,4,5,6,
Laparoscopic										
Musculo-skeletal Conventional		N		N		N	N		1, 2	3,4,5,6
Musculo-skeletal Superficial		N		N		N	N		1, 2	3,4,5,6
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
1: Combined modes include: B+Color,
2: Combined modes include: B+ ShearWave™ Elastography
3: Harmonic Imaging
4: Spatial Compounding
5: ShearWave™ Elastography
6: Imaging Guidance for Biopsies

Prescription Use __XX__ OR Over The Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091970

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K091970
Device Name: **SL 15-4** Transducer (1D Linear Array Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows: :

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Notes
Ophthalmic										
Fetal										
Abdominal		N		N		N	N		1, 2	3,4,5,6
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Breast, Thyroid, Testicle, Prostate)		N		N		N	N		1, 2	3,4,5,6
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N		N		N	N		1, 2	3,4,5,6
Laparoscopic										
Musculo-skeletal Conventional		N		N		N	N		1, 2	3,4,5,6
Musculo-skeletal Superficial		N		N		N	N		1, 2	3,4,5,6
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
1: Combined modes include: B+Color,
2: Combined modes include: B+ ShearWave™ Elastography
3: Harmonic Imaging
4: Spatial Compounding
5: ShearWave™ Elastography
6: Imaging Guidance for Biopsies

Prescription Use __XX__ OR Over The Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
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