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510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21 CFR, part 807, Subpart E, Section 807.92.

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

Ardent Sound, Inc.
33 South Sycamore St.
Mesa, AZ 85202

Corresponding Official: Paul Jaeger
Sr. Principal Engineer
E-mail: p.jaeger@ardentsound.com
Telephone: 480-649-1806
Facsimile: 480-649-1605
Date of preparation: December 20, 2005

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

Seeker/Spark Ultrasound System

Classification: Regulatory Class II
Review Category: Tier II

	<u>21 CFR#</u>	<u>Prod. Code</u>
Ultrasonic Pulsed Echo Imaging System	892.1560	PC 90-IYO
Diagnostic Ultrasonic Transducer	892.1570	PC 90-ITX

Substantial equivalence claimed to:

<u>Trade Name</u>	<u>Manufacturer</u>	<u>510(k)</u>
DIASUS	Dynamic Imaging Ltd	K013142
AU5	Esaote	K980468
AU5/3D	Esaote	K000681

The Seeker/Spark is of comparable type and substantially equivalent to the legally marketed

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Dynamic Imaging Diasus, Esaote AU5 Ultrasound Imaging System and AU5 with 3D Imaging Mode. It has the same technology characteristics, is comparable in key safety and effectiveness features, and all its intended uses and operating modes are available in the predicate devices.

Additional Substantial Equivalence Information is provided in the following Comparison to Predicate Devices table (section 4.5).

Description:

The devices referenced in this submission represent a transportable, software-controlled, diagnostic ultrasound system with accessories. This submission does not include technology or control feature changes nor deviations from indications for use different from those demonstrated in previously cleared devices operating in ultrasound B-Mode or M-Mode, inclusive of the predicate devices so claimed.

The devices included in this submission are as follows:

Seeker/Spark Ultrasound System utilizing as hardware and firmware an ultrasound engine contained in a stand-alone enclosure with separate control panel, for connection to a host PC via a USB port;

A probe, 128 element convex array (for Seeker only), at an ultrasonic frequency of approximately 4 MHz, model CLA4, part number 9650-0003.

A probe, 128 element convex endocavity array at an ultrasonic frequency of approximately 6.5 MHz, model ENDO-6.5, part number 9650-0001.

A probe, 128 element linear array at an ultrasonic frequency of approximately 10 MHz, model L10, part number 9655-0003.

A probe, 128 element linear array at an ultrasonic frequency of approximately 12 MHz, model L12, part number 9655-0002.

A probe, 128 element linear array at an ultrasonic frequency of approximately 16 MHz, model HFLA, part number 9655-0004.

Software able to reside in a Windows-based PC inclusive of a non-metrological 3-D image rendering capability.

Seeker/Spark complies with the following standards:

- a) IEC 60601-1, Part 1: General requirements for safety.

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- b) IEC 60601-1-2, Part 1: General requirements for safety, 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.
- c) IEC 60601-1-4, Part 1: General requirements for safety, 4. Collateral standard: Programmable electrical medical systems.
- d) IEC 60601-2-37:2004-08 Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

Intended use:

The intended uses of this system and its accessories are as follows:

B and M-mode imaging for: Fetal, Abdominal, 3-D Visualization (non-measuring), Small organ, Pediatric, Cephalic, Transrectal, Transvaginal, Musculoskeletal (conventional and superficial), Peripheral Vessel and Needle Guidance.

Summary of technological characteristics:

There are no technological characteristics or features or indications for use in this Submission that are not previously evaluated and approved in the predicate devices, nor are there such technologies, features and indications for use not commonly used in the practice of diagnostic ultrasound.

Testing:

The Seeker/Spark Ultrasound System and its accessories are designed for compliance to all applicable medical devices safety standards, as referenced in Section 4. Prior to release for manufacturing, all such devices, so designed, are tested and determined to be in full compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness. No additional clinical testing is required, as the indications for use are not a novel indication as shown by the predicate devices in Section 3. The modes of operation for this system are limited to B-mode, M-Mode and combined B-M mode.

Ardent Sound, Inc. believes that the acoustic testing, conformance to the standards listed herein and Ardent's compliance to 21 CFR 820 Good Manufacturing Practices, both confirm and ensure the substantial equivalence with respect to safety and effectiveness to the predicate devices identified.

510(k) Number: None currently exists.

Device Name: Seeker/Spark Ultrasound System



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Ardent Sound, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K060800
Trade/Device Name: Seeker/Spark Ultrasound Imaging System
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasound pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulatory Class: II
Dated: March 20, 2006
Received: March 24, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) 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 Seeker/Spark Ultrasound Imaging System as described in your premarket notification:

CLA4, 4 MHz 60mm ROC, 128 element Convex Array, PN 9650-0003
ENDO-6.5, 6.5 MHz 128 element Convex Endocavity Array, PN 9650-0001
L10, 128 element 10 MHz Linear Array, PN 9655-0003
L12, 128 element 12 MHz Linear Array, PN 9655-0002
HFLA, 128 element 12-18 MHz High Frequency Linear Array, PN 9655-0004

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

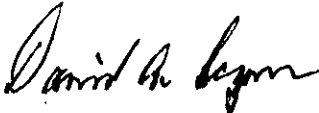
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Page 3 – Ms. Laura Storms-Tyler

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,



for David H. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

INDICATIONS FOR USE

K060800

Diagnostic Ultrasound Indications for Use Form

System: **Seeker and Spark Ultrasound Imaging System**

Transducer:

Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N						N B/M	3D
Abdominal		N	N						N B/M	3D
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N B/M	
Small Organ (specify)		N Note 1							N B/M	
Neonatal Cephalic		N	N						N B/M	
Adult Cephalic		N	N						N B/M	
Cardiac										
Transesophageal										
Transrectal		N	N						N B/M	
Transvaginal		N	N						N B/M	
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N B/M	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N B/M	
Musculo-skeletal Superficial		N	N						N B/M	
Other (specify)										

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

Additional Comments: Note 1 Breast, Thyroid, Testicles

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Concurrence of CDRH Office of Device Evaluation

[Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number *K060800*

K060800

Diagnostic Ultrasound Indications for Use Form

System: **Seeker Ultrasound Imaging System**
 Transducer: **CLA4, 4 MHz 60mm ROC, 128 element convex array, PN 9650-0003.**
 Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N						N B/M	3D
Abdominal		N	N						N B/M	3D
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Seymour

 (Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number *K060800*

Diagnostic Ultrasound Indications for Use Form

K060800

System: **Seeker and Spark Ultrasound Imaging System**
 Transducer: **ENDO-6.5, 6.5 MHz 128 element convex endocavity array, PN 9650-0001.**
 Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

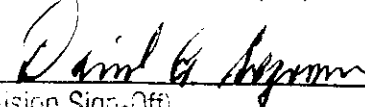
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N						N B/M	3D
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N						N B/M	
Transvaginal		N	N						N B/M	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: _____

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 510(k) Number K060800

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

R060800

System: **Seeker and Spark Ultrasound imaging System**
 Transducer: **L10, 128 element 10 MHz linear array, PN 9655-0003.**
 Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N B/M	
Small Organ (specify)		N Note 1							N B/M	
Neonatal Cephalic		N	N						N B/M	
Adult Cephalic		N	N						N B/M	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N B/M	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N B/M	
Musculo-skeletal Superficial		N	N						N B/M	
Other (specify)										

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

Additional Comments: Note 1 Breast, Thyroid, Testicles

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. [Signature]
 (Division Sign-Off)
 Division of Reproductive, Abdominal, and
 Radiological Devices
 510(k) Number *R060800*

K060800

Diagnostic Ultrasound Indications for Use Form

System: **Seeker and Spark Ultrasound Imaging System**
 Transducer: **L12, 128 element 12 MHz linear array, PN 9655-0002.**
 Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N B/M	
Small Organ (specify)		N Note 1		N Note 1					N B/M	
Neonatal Cephalic		N	N						N B/M	
Adult Cephalic		N	N						N B/M	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N B/M	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N B/M	
Musculo-skeletal Superficial		N	N						N B/M	
Other (specify)										

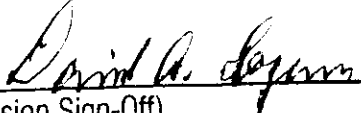
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K060800

Diagnostic Ultrasound Indications for Use Form

System: **Spark Ultrasound Imaging System**
 Transducer: **HFLA, 128 element 12-18MHz High Frequency Linear Array, PN 9655-0004**
 Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N B/M	
Small Organ (specify)		N Note 1							N B/M	
Neonatal Cephalic		N	N						N B/M	
Adult Cephalic		N	N						N B/M	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N B/M	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N B/M	
Musculo-skeletal Superficial		N	N						N B/M	
Other (specify)										

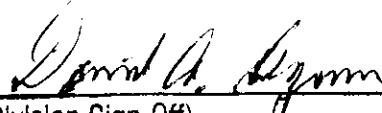
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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 510(k) Number K060800