ARDENT
(((SOUND)))

K092182

OCT - 9 2009

510(k) Summary:

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 using FDA Guidance Document: "Information for Manufacturers Seeking Marketing Clearance for Ultrasound Systems and Transducers", September 09, 2008.

This submission includes the addition of M-Mode Capabilities and an Endocavity probe (for Transvaginal and Transrectal Imaging) to the Voyager Compact Imaging System (K050551)

Company Name: Ardent Sound Inc.
Company Address: 33 S. Sycamore Street
Mesa, AZ 85202-1150 USA

Corresponding Official: **Deborah Van Gorder**
Quality Specialist
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Date of preparation: March 18, 2009

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: Voyager Compact Imaging Device

Classification: Regulatory Class II
Review Category: Tier II

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

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Substantial equivalence claimed to:

Trade Name	Manufacturer	510(k)
Tringa 50S	Pie Medical	K020112
AU5	Esaote	K980468
AU5/3D	Esaote	K000681

The Voyager is of comparable type and substantially equivalent to the legally marketed Pie Medical 50s Tringa, Esaote AU5 Ultrasound Imaging System, 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 predicative devices.

Description:
The devices referenced in this submission represent a highly portable, software-controlled, diagnostic ultrasound system with accessories. This submission does not include technology or control feature changes or deviations from indications for use different from those demonstrated in previously cleared devices, inclusive of the predicate devices so claimed.

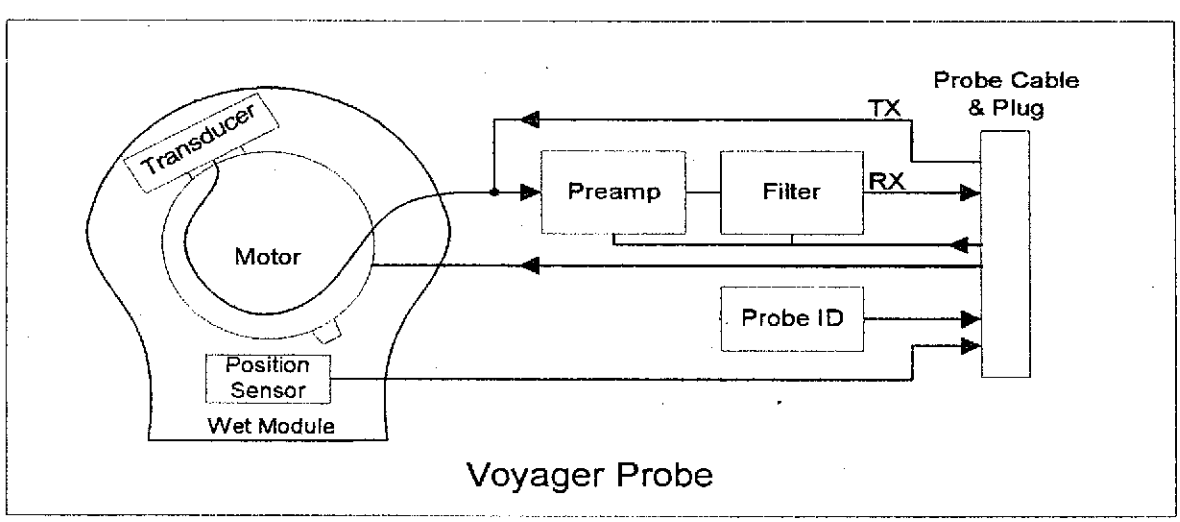
The devices included in this submission are as follows:

Voyager Ultrasound System utilizing as hardware and firmware an ultrasound engine contained in a very small in-line enclosure with only an 'image-freeze' control button;

A probe, C-4, of a mechanical configuration providing a single crystal sector scan, or M-mode operation, at an ultrasonic frequency of approximately 4 (±12%) MHz;

A probe, C-10, a mechanical configuration providing a single crystal sector scan, or M-mode operation, at an ultrasonic frequency of approximately 8.0 (±20%) MHz;

A probe EC, a mechanical configuration providing a single crystal sector scan, or M-mode operation, at an ultrasonic frequency of approximately 8.0 (±20%) MHz.



Voyager Probe

Software able to reside in a laptop inclusive of a non-metrological 3-D image rendering capability and, a means to enable the use of needle guidance techniques on each probe model.

Patient Contact Materials:

The following certified patient contact materials are unchanged in formulation and processing remaining FDA compliant. Declaration of Conformity, section 1.7.3. Biocompatibility data to be maintained in the Design History File, under Documentation Control.

Trade Name	Generic Material	Biocompatibility data
DOW 732 Multi-Purpose Sealant - Clear	Silicone Elastomer	Complies with FDA Regulation 21 CFR 177.2600 for incidental contact with food. National Sanitation Foundation List 51, for direct food contact, and List 61, for use with potable water. Recognized under UL QMFZ2 / 510(k) K003479
HDPE	Polyethylene, High Density	Complies with FDA Regulation 21 CFR 177. 1520 for incidental contact with food. Technical Data located in DHF.
RP-6405	Polyurethane Hardener	Biocompatibility tests performed by NamSA, Material passed all ISO-10993-1 FDA Requirements. Copy of results maintained in DHF. 510(k) K924458
RP-6401	Polyurethane	Biocompatibility tests performed by NamSA, Material passed all ISO-10993-1 FDA Requirements. Copy of results maintained in DHF. 510(k) K924458
Coaxial Cable	Medical Grade PVC	Coast Wire & Plastic Tech., Inc. Manufacturer certifies ISO-10993-1 FDA Compliant #60-0600-24.Technical Data located in DHF
Absylux	ABS Acrylonitrite-butadiene-styrene	Westlake Plastics Compangy Manufacturer certifies ISO-10993-1 FDA Compliant #60-0600-24. Technical Data located in DHF
FullCure 720	Acrylic-based photpolymer	Objet Geometries, Ltd. Manufacturer certifies ISO-10993-1. Technical Data located in DHF
SterAlloy 2463	Urethane	Napco, Inc. Manufacturer certifies ISO-10993-1.Technical Data located in DHF
RentCast-6400-1	Urethane	Huntsman Advanced Materials America ertifies ISO-10993-1.Technical Data located in DHF

Voyager complies with the following standards:

a) FDA Standards #: 12-66 – AIUM "Medical Ultrasound Standard", Dated 06/01/2004
b) FDA Standards #: 12-105 – NEMA "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment", dated 09/01/2004
c) FDA Standards #: 12-139 – AIUM "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment", dated 03/31/2006
d) FDA Standards #: 12-182 – IEC "Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment", dated 07/31/2008
e) FDA Standards #: 5-4: IEC 60601-1, Part 1: General requirements for safety.

f) FDA Standards # 5-35: IEC 60601-1-2, Part 1: General requirements for safety, 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.

g) FDA Standards # 5-41 IEC 60601-1-4, Part 1: General requirements for safety, 4. Collateral standard: Programmable electrical medical systems.

h) FDA Standards #: 2-98: ISO 10993-1:2003, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing."

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

Imaging, using B-mode, M-mode: Fetal, Abdominal, 3-D Visualization (non-measuring), Small organ (thyroid and breast), Musculoskeletal (Conventional), Peripheral Vessel, Transvaginal, Transrectal 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 Voyager Ultrasound System and its accessories are designed for compliance to all applicable medical devices safety standards, as referenced above. Prior 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 1.5. The additional mode of operation for this system is M-mode. The additional probe is the EC endocavity Probe for Transvaginal and Transrectal imaging with non-measuring 3D and Needle Guidance.

Acoustic Test Result Summary:

Probe Model	$I_{SPTA.3}$ [mW/cm^2]	TI Type	TI Value	MI	$I_{pa.3}@MI_{max}$ [W/cm^2]
C4	15.8	TIS	0.05	0.30	21.3
C10*	27.7	TIS	0.01	0.45	99.7
EC*	27.7	TIS	0.01	0.45	99.7

* C10 and EC Probes utilize the same transducer crystal Configuration

Conclusion:

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT - 9 2009

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

Re: K092182
Trade/Device Name: Voyager Compact Imaging Device
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: September 28, 2009
Received: September 29, 2009

Dear Mr. Job:

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 Voyager Compact Imaging Device, as described in your premarket notification:

Transducer Model Numbers

C4 Probe C10 Probe EC Endocavity Probe, Transvaginal and Transrectal

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Mr. William Jung at (301) 796-5790.

Sincerely yours,

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

Enclosures

Indications for Use Statement

K092182

510(k) Number (if Known): K050551 (Previous Clearance: B-Mode, Needle Guidance, 3D(non-measuring) imaging on the C4 and C10 Transducers)

Device Name: Voyager Compact Imaging Device

Indication for Use:

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

Evaluating Soft Tissue by Ultrasound Imaging, using B-mode and M-mode: for Fetal, Abdominal, 3-D Visualization (non-measuring), Small organ (thyroid and breast), Musculoskeletal (Conventional), Peripheral Vessel, Transvaginal, Transrectal and Needle Guidance.

1. C4 Needle Guide Bracket/Kit (Reusable/Disposable) uses kit K973958
   a. Disinfect or Sterilize per Protek Medical Specifications
2. C10 Needle Guide Bracket/Kit (Reusable/Disposable) uses kit K973958
   a. Disinfect or Sterilize per Protek Medical Specifications
3. EC Needle Guide Kit (Disposable) uses kit K971722 & K971115
   a. Sterile Needle Guide
   b. Sterile Gel
   c. Sterile Probe Cover (Non-Latex)
4. EC Needle Guide Kit (Reusable) uses kit K971722 & K971115
   a. Disinfect or Sterilize per Protek Medical Specifications

Prescription Use √ And/Or Over the Counter Use _____

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

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

Ardent Sound, Inc.
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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092182

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Appendix 1.
Indications for Use System Chart

Previous 510(k) Number: K050551 (Previous Clearance: B-Mode, Needle Guidance, 3d (non-measuring) imaging on the C4 and C10 transducers)

Intended Use: Intended Use: Evaluating ~~Soft Tissue by Ultrasound~~ Imaging, using B-mode, M-mode, & combined BM-mode (non-simultaneous) for **Prescription** Use Only

System: Voyager Compact Imaging System **Transducer:** C4, C10, EC

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B&M-Modes, non-simultaneous Imaging	Other* (Specify) 3D
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**	N				N	P
	Abdominal	P	N				N	P
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify), Breast, Thyroid	P						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N				N	N
	Trans-vaginal	N	N				N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P	N					
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) Needle Guidance	**						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N					
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

** Previously cleared by FDA (K050551) in B-Mode. New Submittal for EC Probe.

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510(k) Number K092182

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Appendix 1:
Indications for Use Probe Chart, C4 Probe

Previous 510(k) Number: K050551 (Previous Clearance: B-Mode, Needle Guidance, 3d (non-measuring) imaging on the C4 and C10 transducers)

Intended Use: Intended Use: Evaluating Soft Tissue by Ultrasound Imaging, using B-mode, M-mode, & combined BM-mode (non-simultaneous) For **Prescription** Use Only

System: Voyager Compact Imaging System **Transducer:** C4 Probe

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) B&M-Modes, non-simultaneous Imaging**	**Other* (Specify) 3D**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	N				N	P
	Abdominal	P	N				N	P
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify), Breast, Thyroid							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) Needle Guidance	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Appendix 1:
Indications for Use Probe Chart, C10 Probe

Previous 510(k) Number: K050551 (Previous Clearance: B-Mode, Needle Guidance, 3d (non-measuring) imaging on the C4 and C10 transducers)

Intended Use: Intended Use: Evaluating Soft Tissue by Ultrasound Imaging, using B-mode, M-mode, & combined BM-mode (non-simultaneous) For **Prescription** Use Only

System: Voyager Compact Imaging System with M-Mode **Transducer:** C-10 Probe

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B&M-Modes, non-simultaneous Imaging	Other* (Specify) 3D
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify), Breast, Thyroid	P						P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P						P
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) Needle Guidance	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P						
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Appendix 1:

Indications for Use Probe Chart, EC Endocavity Probe, Transvaginal & Transrectal

Previous 510(k) Number: K050551 (Previous Clearance: B-Mode, Needle Guidance, 3d (non-measuring) imaging on the C4 and C10 transducers)

Intended Use: Intended Use: Evaluating Soft Tissue by Ultrasound Imaging, using B-mode, M-mode, & combined BM-mode (non-simultaneous) ~~For Prescription Use Only~~

System: Voyager Compact Imaging System with M-Mode **Transducer:** : EC Endocavity Probe, Transvaginal and Transrectal

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B&M-Modes, non-simultaneous Imaging	Other* (Specify) 3D
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N				N	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify), Breast, Thyroid							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N				N	N
	Trans-vaginal	N	N				N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) Needle Guidance	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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