MAR 2 2 2005

K050551

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: February 1, 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

Voyager Ultrasound 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

Substantial equivalence claimed to:

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

The Voyager is of comparable type and substantially equivalent to the legally marketed

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 predicative devices.

Additional Substantial Equivalence Information is provided in the following Comparison to Predicate Devices table.(Page 17, Table 2.)

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 nor deviations from indications for use different from those demonstrated in previously cleared devices operating in ultrasound B-Mode, 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 of approximately 8 frames per second at an ultrasonic frequency of approximately 4 MHz;

A probe, C-10, a mechanical configuration providing a single crystal sector scan of approximately 8 frames per second at an ultrasonic frequency of approximately 10 MHz;

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.

Voyager complies with the following standards:

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

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 use of this system and its accessories are as follows (all derived from B-Mode operation):

Imaging: Fetal, Abdominal, 3-D Visualization (non-measuring), Small organ (thyroid and breast), Musculoskeletal (Conventional), 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 Voyager Ultrasound System and its accessories are designed for compliance to all applicable medical devices safety standards, as referenced in Section 4. 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 3. The modes of operation for this system are limited to B-mode exclusively.

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: Voyager
Compact Imaging Device

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2005

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

Re: K050551
Trade Name: Voyager™ Compact Imaging Device
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Dated: February 28, 2005
Received: March 3, 2005

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™ Personal Imaging Device, as described in your premarket notification:

Transducer Model Number

C-10, 10MHz sector scan probe, 9375-0002
C-4, 4MHz sector scan probe, 9375-0001

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 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.

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo Perez at (301)594-1212.

Sincerely yours,

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

Enclosure

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System: **Voyager Compact Imaging Device**

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								3 D
Abdominal		N								
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		**N - Thyroid and Breast**								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		**N**								
Laparoscopic										
Musculo-skeletal Conventional		**N**								
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050551

Diagnostic Ultrasound Indications for Use Form

System: **Voyager Compact Imaging Device**

Transducer: **C-10, 10MHz sector scan probe, 9375-0002**

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										
Small Organ (specify)		N - Thyroid and Breast								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional		N								
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050551

Diagnostic Ultrasound Indications for Use Form

System: **Voyager Compact Imaging Device**
Transducer: **C-4, 4MHz sector scan probe, 9375-0001**
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								3D
Abdominal		N								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:_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Lagowski

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050351