K120321

FEB 17 2012

Summary of Safety and Effectiveness

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

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

Rob Butler
Senior Manager, Regulatory Affairs
Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA 01810-6302
Tel: (978) 659-2785
Fax: (978) 975-7324

Date prepared: January 26, 2012.

Manufacturer's Name, Manufacturing Name, and Initial distributor:

Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

Establishment Registration Number:

Philips Ultrasound, Inc. 1217116

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 and transducers

Proprietary Name: ClearVue 350/550 Diagnostic Ultrasound System

Classification Name: Class II

21 CFR Section	Classification Name	Product Code
892.1550	System, Imaging, Pulsed Doppler, Ultrasonic	90 IYN
892.1560	System, Imaging, Pulsed Echo, Ultrasonic	90 IYO
892.1570	Transducer, Ultrasonic, diagnostic	90 ITX

3) Substantially Equivalent Device

HD11 Diagnostic Ultrasound System K043535

3) Device Description

ClearVue 350/550 is a new general imaging or shared-service ultrasound system from Philips Ultrasound. The 550 model has more complete features than the 350, and an articulating arm for mounting of the display (the 350 has a tilt-swivel mount for the display). ClearVue provides excellent ultrasound capabilities in a lightweight, affordable system. Its intended use and indications for use are standard for general imaging and shared-service (general imaging + cardiac) systems, and are within the cleared intended use and indications for use for the Philips HD11 diagnostic ultrasound system (cleared in K043535), to which ClearVue is substantially equivalent.

4) Intended Use

ClearVue 350/550 is intended for diagnostic ultrasound imaging and fluid flow analysis.

5) Technological comparison to predicate devices

Philips ClearVue 350/550 and HD11 Diagnostic Ultrasound Systems are Track 3 systems that employ the same fundamental scientific technology.

6) Determination of Substantial Equivalence

Non-clinical performance data

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance
- IEC 60601-1-1: Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- ISO 10993: Biological evaluation of medical devices.

Summary of Clinical Tests

ClearVue 350/550 introduces no new indications for use, modes, features, or technologies relative to the predicate device (HD11- K0433535) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

7) Conclusions

Philips ClearVue 350/550 is substantially equivalent in safety and effectiveness to the predicate identified above:

- The predicate device and ClearVue 350/550 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The predicate device and ClearVue 350/550 have the same gray-scale and Doppler capabilities.
- The predicate device and ClearVue 350/550 use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate device and ClearVue 350/550 have acoustic output levels below the Track 3 FDA limits.
- The predicate device and ClearVue 350/550 are manufactured under equivalent quality systems.
- The predicate device and ClearVue 350/550 are manufactured of materials with equivalent bio safety. The materials have been evaluated and found to be safe for this application.
- The predicate device and ClearVue 350/550 are designed and manufactured to the same electrical and physical safety standards.

514 Performance Standards

There are no Sec. 514 performance standards for this device.

Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Site(s)

Not applicable. No components supplied sterile.

Reason for Submission

This submission is for the first (1.0) release of the ClearVue 350/550 diagnostic ultrasound system from Philips Ultrasound. This is a new diagnostic ultrasound system, substantially equivalent to the predicate device.

Track

This is a Track 3 system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 17 2012

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K120321
Trade/Device Name: ClearVue 350/550 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO and ITX
Dated: February 1, 2012
Received: February 2, 2012

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 ClearVue 350/550 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

S4-1
C5-2
C9-4v
L12-4

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 895. 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 Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary S Pastel for

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): K120321

Device Name: _ClearVue 350/550 Diagnostic Ultrasound System_____

Indications for Use: The ClearVue 350/550 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in the following modes: B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Harmonics, iSCAN, X-Res, angio, 3D (freehand), and SonoCT. The system may also be used in biopsy guidance and to assist in infertility monitoring of follicle development (OB). The system is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications, as listed in FDA's Diagnostic Ultrasound Indications for Use Forms (included in the submittal):

Fetal / Obstetric
Abdominal
Pediatric
Small Organ (thyroid, scrotum, prostate, breast)
Neonatal Cephalic
Adult Cephalic
Trans-rectal
Trans-vaginal
Musculoskeletal (conventional)
Musculoskeletal (superficial)
Other – Gynecological
Cardiac Adult
Cardiac Pediatric
Cardiac Other - Fetal
Peripheral Vessel
Peripheral Vessel Other – Carotid

The clinical environments where the ClearVue 350/550 Diagnostic Ultrasound System can be used include hospital, clinical and medical office settings for diagnosis of patients. The use models for ClearVue 350/550 are within the scope of and substantially equivalent to current indications for use for Diagnostic Ultrasound System.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K120321

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: ClearVue 350/550 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N	N	N	N	N(1-7)
	Abdominal	N	N	N	N	N	N	N(1-7)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N(1-7)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N	N	N	N	N(1-7)
	Neonatal Cephalic	N	N	N	N	N	N	N(1-7)
	Adult Cephalic	N	N	N	N	N	N	N(1-7)
	Trans-rectal	N	N	N		N	N	N(2-7)
	Trans-vaginal	N	N	N		N	N	N(2-8)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N	N	N	N	N(1-7)
	Musculo-skel (superficial)	N	N	N	N	N	N	N(1-7)
	Other (Gynecological)	N	N	N	N	N	N	N(1-8)
Cardiac	Cardiac Adult	N	N	N	N	N	N	N(1-3,5,7)
	Cardiac Pediatric	N	N	N	N	N	N	N(1-3,5,7)
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N	N	N	N	N(1-7)
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N(1-7)
	Other (Carotid)	N	N	N	N	N	N	N(1-7)

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

***Other modes:** 1. Tissue Harmonics 2. iSCAN 3. X-Res 4. Angio imaging	5. 3D (Freedhand) Imaging 6. SonoCT 7. Biopsy guidance 8. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: none	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120321

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: S4-1 transducer used with ClearVue 350/550 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N	N	N	N	N(1-5,7)
	Abdominal	N	N	N	N	N	N	N(1-5,7)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N(1-5,7)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	N	N	N	N	N	N	N(1-5,7)
	Adult Cephalic	N	N	N	N	N	N	N(1-5,7)
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N	N	N	N	N(1-5,7,8)
Cardiac	Cardiac Adult	N	N	N	N	N	N	N(1-3,5,7)
	Cardiac Pediatric	N	N	N	N	N	N	N(1-3,5,7)
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N	N	N	N	N(1-3,5,7)
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

***Other modes:** 1. Tissue Harmonics 2. iSCAN 3. X-Res 4. Angio imaging	5. 3D (Freehand) Imaging 6. SonoCT 7. Biopsy guidance 8. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: none	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120321

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: C5-2 transducer used with ClearVue 350/550 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N(1-7)
	Abdominal	N	N	N		N	N	N(1-7)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N(1-7)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N(1-7)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N		N	N	N(1-8)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N		N	N	N(1-7)
Peripheral Vessel	Peripheral vessel							
	Other (specify)							

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

***Other modes:** 1. Tissue Harmonics 2. iSCAN 3. X-Res 4. Angio imaging	5. 3D (Freehand) Imaging 6. SonoCT 7. Biopsy guidance 8. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD	
Previous submission: none	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120321

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: C9-4v transducer used with ClearVue 350/550 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N(2-7)
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N(2-7)
	Trans-vaginal	N	N	N		N	N	N(2-8)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N		N	N	N(2-8)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

***Other modes:** 1. Tissue Harmonics 2. iSCAN 3. X-Res 4. Angio imaging	5. 3D (Freehand) Imaging 6. SonoCT 7. Biopsy guidance 8. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD	
Previous submission: none	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K k120321

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: L12-4 transducer used with ClearVue 350/550 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N(1-7)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N(1-7)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N(1-7)
	Musculo-skel (superficial)	N	N	N		N	N	N(1-7)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N(1-7)
	Other (Carotid)	N	N	N		N	N	

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

***Other modes:** 1. Tissue Harmonics 2. iSCAN 3. X-Res 4. Angio imaging	5. 3D (Freehand) Imaging 6. SonoCT 7. Biopsy guidance 8. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+Color+PWD	
Previous submission: none	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

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510K K120321