



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

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

December 16, 2015

Re: K153480
Trade/Device Name: ClearVue 850 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 30, 2015
Received: December 2, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153480

Device Name

ClearVue 850 Diagnostic Ultrasound System

Indications for Use (Describe)

The ClearVue850 Diagnostic Ultrasound system is a general purpose, portable, cart based ultrasound system, intended for use by customers in various clinical settings (private offices, clinics, small hospitals, large hospitals, primary and community healthcare centers) by different users (General Practitioners, Paraprofessionals, physician specialists including OBG's, Ultrasound Lab physicians, and nurse practitioners, etc.,

The 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), 4D and SonoCT, Combined modes includes FloVue, Elastography (strain).

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 Form section 1.3 which includes Fetal / OB, Abdominal, Pediatric, Small Organ (breast, thyroid, testicle), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Musculo-skel. (Superficial), Other: GYN, Other: Urology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Other (Fetal Echo), Peripheral vessel and Cerebral Vascular.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue 850 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6,7,8,9,10,11
	Abdominal	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11,13,16
	Neonatal Cephalic	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11
	Adult Cephalic	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11
	Trans-rectal	N	N	N		N	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Trans-vaginal	N	N	N		N	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11,16
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11,16
Intra-luminal								
Other: GYN	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11	
Other: Urology	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6, 7, 8,9,10,11	
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 8,9,11,12
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 8,9,11,12
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6,8,9,11,12
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note: 1,2,3,4,15	Note: 5,6,7,8,9,10,11,14,16
	Cerebral Vascular	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6,8,9,10,11,12

N= new indication; P= previously cleared by FDA

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue 850 Diagnostic Ultrasound System

Transducer: C5-2

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PW D	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
Other: Urology		P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
Peripheral Vessel	Peripheral Vessel	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K120321

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue 850 Diagnostic Ultrasound System

Transducer: V6-2

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11
Other: Urology		P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,8, 9,10,11
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8, 9,10,11
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K120321

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue850 Diagnostic Ultrasound System

Transducer: C9-4v

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K120321

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue850 Diagnostic Ultrasound System

Transducer: 3D9-3v

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,10,11	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K120321

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue850 Diagnostic Ultrasound System

Transducer: L12-4

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6, 7, 8,9,10,11
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K120321

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue850 Diagnostic Ultrasound System

Transducer: L12-5

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,7,8,9,10,11,16
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,7,8,9,10,11,13,16
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,7,8,9,10,11,16
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,7,8,9,10,11,16
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3,15	Note: 5,7,8,9,10,11,,14,16
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K132304

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue 850 Diagnostic Ultrasound System

Transducer: S4-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
	Abdominal	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
	Adult Cephalic	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 8,9,10,11,12
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 8,9,10,11,12
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11
	Cerebral Vascular	P	P	P	P	P	Note: 1,2,3,4	Note: 6, 8,9,10,11

N= new indication; P= previously cleared by FDA K120321

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: ClearVue850 Diagnostic Ultrasound System

Transducer: D2cwc

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult					P		
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA- K132304

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 10: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 11: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 12: TDI
Note 5: SonoCT	Note 13: Elastography
Note 6: Imaging for guidance of biopsy	Note 14: FloVue
Note 7: Panoramic Imaging	Note 15: Combined modes include: B+FloVue+PWD
Note 8: Color Power Angio (CPA)	Note 16: AutoSCAN

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

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

Prescription Use (Per 21 CFR 801.109)

Philips Ultrasound, Inc.	Quality, Regulatory and Sustainability	Doc. ID:	238512
	ClearVue850 Traditional 510(k)	Revision:	A
		Doc. date:	2015 Sep 30
		Page	16 of 96

510(k) 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

Saraswathi Deora
Program Manager- Q&R-Regulatory Affairs
Saraswathi.Deora@philips.com
On Behalf of:
Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

Date prepared: September 30, 2015

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: ClearVue850

Classification: Class II

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

3) Substantially Equivalent Devices

Primary Predicate Device

Philips ClearVue Diagnostic Ultrasound System	K120321	02/17/2012
---	---------	------------

Reference Device

Philips EPIQ Diagnostic Ultrasound System	K132304	08/21/2013
GE LOGIQ S7 Expert and LOGIQ S7 Pro	K141261	06/05/2014

Copies are uncontrolled

Philips Ultrasound, Inc.	Quality, Regulatory and Sustainability ClearVue850 Traditional 510(k)	Doc. ID:	238512
		Revision:	A
		Doc. date:	2015 Sep 30
		Page	17 of 96

4) Device Description

The ClearVue850 Diagnostic Ultrasound System is a general purpose, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation.

The ClearVue 850 System is substantially equivalent to the currently marketed and predicate ClearVue350/550 system(K120321) in terms of design and fundamental scientific technology. The ClearVue850 Model is provided with additional transducers D2CWC and L12-5 and software features and additional modes. The software features of the ClearVue 850 System include -Live Panoramic Imaging, FloVue, Strain Elastography Imaging, Curved ROI Tool, QLAB plug-ins IMT and GI3DQ, Stress Echo protocol.

The ClearVue 850 System supports CW Doppler transducer with external CW adapter module which gets attached to the SAM transducer connector, an Up/down mechanism for control panel. The system is designed to be highly reliable and easily serviceable.

5) Intended Use

The ClearVue850 system is a general purpose, portable, cart based ultrasound system, intended for use by customers in various clinical settings (private offices, clinics, small hospitals, large hospitals, primary and community healthcare centers) by different users (General Practitioners, Paraprofessionals, physician specialists including OBG's, Ultrasound Lab physicians, and nurse practitioners, etc.,

The ClearVue850 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), 4D and SonoCT, Combined modes includes FloVue, Elastography (strain).

The ClearVue850 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 Form section 1.3 which includes Fetal / OB, Abdominal, Pediatric, Small Organ (breast, thyroid, testicle), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Musculo-skel. (Superficial), Other: GYN, Other: Urology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Other (Fetal Echo), Peripheral vessel and Cerebral Vascular

6) Comparison of the Design and Technological characteristics

A comparison of the design and technological characteristics of the ClearVue 850 System to the currently marketed and predicate ClearVue 350/550 is provided in Table 1 below:

Philips Ultrasound, Inc.	Quality, Regulatory and Sustainability	Doc. ID:	238512
	ClearVue850 Traditional 510(k)	Revision:	A
		Doc. date:	2015 Sep 30
		Page	18 of 96

Technological Characteristics

Feature	Proposed ClearVue850 System	Predicate ClearVue350/550 (K120321)
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows
Indication for Use		
	Fetal/Obstetric	Fetal/Obstetric
	Abdominal	Abdominal
	Pediatric	Pediatric
	Small Organ (breast, thyroid, testicle)	Small Organ (prostate)
	Neonatal Cephalic	Neonatal Cephalic
	Adult Cephalic	Adult Cephalic
	Trans-rectal	Trans-rectal
	Trans-vaginal	Trans-vaginal
	Musculo-skel. (Conventional)	Musculo-skel (conventional)
	Musculo-skel. (Superficial)	Musculo-skel (superficial)
	Other (Gynecological)	Other (Gynecological)
	Cardiac Adult	Cardiac Adult
	Cardiac Pediatric	Cardiac Pediatric

Philips Ultrasound, Inc.	Quality, Regulatory and Sustainability	Doc. ID:	238512
	ClearVue850 Traditional 510(k)	Revision:	A
		Doc. date:	2015 Sep 30
		Page	19 of 96

	Other (Fetal Echo)	Other (Fetal)
	Peripheral vessel	Peripheral vessel
	Cerebral Vascular	-
	Other: Urology	-
	Other (Carotid)	Other (Carotid)
	-	-
	-	-
	-	-
	-	-
	-	-
	-	-
Transducer Types	S4-1 Sector Array C5-2 Curved Array C9-4v Curved Array L12-4 Broadband Sector Linear Array 3D9-3V V6-2 L12-5 D2CWc	S4-1 Sector Array C5-2 Curved Array C9-4v Curved Array L12-4 Broadband Sector Linear Array 3D9-3V V6-2
Transducer Frequency	1-12Mhz	1-12Mhz
Modes of Operation	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), 4D and SonoCT, Combined	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

Copies are uncontrolled

Philips Ultrasound, Inc.	Quality, Regulatory and Sustainability ClearVue850 Traditional 510(k)	Doc. ID: 238512 Revision: A Doc. date: 2015 Sep 30 Page 20 of 96
--------------------------	--	--

	modes includes FloVue, Elastography (strain).	(freehand), and SonoCT.
PW Doppler	Available	Available
CW Doppler	Available	Available
Patient contact materials	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible
510(k) Track	Track 3	Track 3
Regulatory Class	Class II	Class II

ClearVue850 System is a Track 3 system that employs the same fundamental scientific technology as that cleared with currently marketed and predicate ClearVue 350/550 (K120321) System and EPIQ K132304 System. The primary difference between ClearVue 350/550/650 (K120321) and ClearVue850 System submitted with this 510(k) is the addition of the L12-5 (K132304) and D2CWC (K132304) with an equivalent additional indication for use.

Elastography Indication for use is already cleared with EPIQ K132304. Flo Vue is a new indication for use in the proposed ClearVue850 System. FloVue from Philips is substantially equivalent to the coded pulse mode of currently marketed and reference GE K141261. Both FloVue and coded pulse helps in simultaneous imaging of tissue and blood flow.

6) Determination of Substantial Equivalence

Non-clinical performance data

Non-clinical tests performed on in this premarket notification submission for a determination of substantial equivalence demonstrates compliance with the following standards:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance
- 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

Quality assurance measures applied to the system design and development include, but were not limited to the following:

- Risk Analysis
- Product Specifications

Philips Ultrasound, Inc.	Quality, Regulatory and Sustainability ClearVue850 Traditional 510(k)	Doc. ID: 238512 Revision: A Doc. date: 2015 Sep 30 Page 21 of 96
--------------------------	--	--

- Design Reviews
- Verification and Validation

Summary of Clinical Tests

The ClearVue850 System introduces no new indications for use, modes, features, or technologies as compared to the currently marketed and predicate devices (EPIQ/ClearVue) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both the currently marketed predicate and subject devices.

7) Conclusions

ClearVue850 is substantially equivalent to the currently marketed and predicates in terms of indications for use, design, indications for use and technological characteristics.

ClearVue 850 is same as ClearVue (K120321) and EPIQ (K130304) transducers L12-5 and D2CWC and additional indications.

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.

Track

This is a Track 3 system