DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 14, 2016

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

Re: K162329
Trade/Device Name: CX50 Diagnostic Ultrasound System, Sparq 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: August 17, 2016
Received: August 19, 2016

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,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number *(if known)* K162329

Device Name

CX50 Diagnostic Ultrasound System

Indications for Use *(Describe)*

Philips CX50 Diagnostic Ultrasound Systems is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Intraoperative
Laparoscopic
Fetal
Abdominal
Pediatric
Small Organ
Adult Cephalic
Neonatal Cephalic
Trans-vaginal
Musculo-skeletal
Gynecological
Cardiac Adult
Cardiac Pediatric
Trans-Esoph. (Cardiac)
Intracardiac echo
Peripheral Vessel
Other (Carotid)

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

X Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: CX50 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	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric	**P**	**P**	**P**	**P**	**P**	**P**	**P** (1,3-8)
	Abdominal	**P**	**P**	**P**	**P**	**P**	**P**	**P** (1,3-9)
	Intraoperative (vascular/epicardial)	**P**	**P**	**P**		**P**	**P**	P (1,3,4,5,7)
	Intraoperative (Neuro)							
	Laparoscopic	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**(1-8)
	Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P** (1,3-7)
	Trans-rectal							
	Trans-vaginal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
Cardiac	Cardiac Adult	**P**	**P**	**P**	**P**	**P**	**P**	**P**(1-4)
	Cardiac Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-7)**
	Trans-esoph. (Cardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P**(1-4)
	Other (Intracardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P** (1-7)
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**	**P**	**P**	**P**	**P** (1,3-8)
	Other (Carotid)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue or Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

(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 FORM

510(k) Number: _____

Device name: C5-1 transducer for use with CX50 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	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:** 1. Harmonics (Tissue & Contrast) 2. Tissue Doppler Imaging 3. iSCAN 4. X-Res	5. Angio Imaging 6. 3D Imaging 7. SonoCT 8. Biopsy guidance 9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: C8-5 transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P (1,3-9)**
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**
	Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P (1-8)**
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**
	Other (Carotid)	**P**	**P**	**P**		**P**	**P**	**P (1,3-8)**

N= new indication; P= previously cleared by FDA

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: C9-3io transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Intraoperative (vascular/epicardial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: C9-3v transducer for use with CX50 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	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: C10-3v transducer for use with CX50 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	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: D2cwc transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult				**P**			
	Cardiac Pediatric				**P**			
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

* Other modes:
Combined modes:
Previous submission: K123754 - CX50

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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 FORM

510(k) Number: _____

Device name: D5cwc transducer for use with CX50 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							
	Intraoperative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric				**P**			**P (1-7)**
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel				**P**			
	Other (Carotid)				**P**			

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

(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 FORM

510(k) Number: _____

Device name: L10-4lap transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac echo)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: L12-3 transducer for use with CX50 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	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P** (1-8)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Other (Carotid)	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)

N= new indication; P= previously cleared by FDA

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: L12-5 50 transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7,8)
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7,8)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P**(1,4,6,7,8)
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P** (1,4, 6,7,8)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7,8)
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7,8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac echo)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P**(1,4,6,7,8)
	Other (Carotid)	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7,8)

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: L15-7io transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: S12-4 transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Abdominal	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P (1-4,6)**
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Cardiac Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: S5-1 transducer for use with CX50 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	**P**	**P**	**P**		**P**	**P**	**P** (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P** (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-8)**
	Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P** (1,3-7)
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	**P**	**P**	**P**	**P**	**P**	**P**	**P**
	Cardiac Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-7)**
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: S7-3t transducer for use with CX50 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							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-5)**
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: S7-3t cleared in K160807 – EPIQ	

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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 FORM

510(k) Number: _____

Device name: S8-3 transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Abdominal	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P (1-4,6)**
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P (1-4,6)**
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P (1-4,6)**
	Other (Gynecological)							
Cardiac	Cardiac Adult	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Cardiac Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4,6)**
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: X7-2t transducer for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-6)**
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: St. Jude Medical ViewFlex Xtra (K121381) for use with CX50 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-7)**
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. 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: K123754 - CX50	

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

Prescription Use (Per 21 CFR 801.109)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number *(if known)* K162329

Device Name

Sparq Diagnostic Ultrasound System

Indications for Use *(Describe)*

Philips Sparq Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Fetal
Abdominal
Pediatric
Small Organ
Adult Cephalic
Trans-vaginal
Trans-rectal
Musculo-skeletal
Gynecological
Cardiac Adult
Trans-Esoph. (Cardiac)
Peripheral Vessel

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

X Prescription Use (Part 21 CFR 801 Subpart D)

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: Philips Ultrasound, Inc. Sparq 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	**N**	**N**	**N**		**N**	**N**	**N (1,3-7)**
Fetal Imaging & Other	Fetal/Obstetric	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3-7)**
	Abdominal	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3-8)**
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3-8)**
	Neonatal Cephalic							
	Adult Cephalic	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3-7)**
	Trans-rectal	**N**	**N**	**N**		**N**	**N**	**N (1,3-7)**
	Trans-vaginal	**N**	**N**	**N**		**N**	**N**	**N (1,3-7)**
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**N**	**N**	**N**		**N**	**N**	**N (1,3-7, 8)**
	Musculo-skel (superficial)	**N**	**N**	**N**		**N**	**N**	**N (1,3-7, 8)**
	Other (Gynecological)	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3-7)**
Cardiac	Cardiac Adult	**N**	**N**	**N**	**N**	**N**	**N**	**N (1-5, 7, 8)**
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3,4)**
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**N**	**N**	**N**	**N**	**N**	**N**	**N (1,3-7, 8)**
	Other (Specify)							

N= new indication; P= previously cleared by FDA

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization*
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K123754 - CX50, K160807 - EPIQ	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: C5-1 transducer for use with Sparq 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	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:** 1. Harmonics (Tissue & Contrast) 2. Tissue Doppler Imaging 3. iSCAN 4. X-Res	5. Angio 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: C6-2 Transducer for use with Sparq 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, breast)	**N**	**N**	**N**		**N**	**N**	**N (1, 3-7)**
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel (conventional)	**N**	**N**	**N**		**N**	**N**	**N (1, 3-7)**
	Musculo-skel (superficial)							
	Intra-luminal							
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
Cardiac	Cardiac Adult	**N**	**N**	**N**		**N**	**N**	**N (1-4, 7)**
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**N**	**N**	**N**		**N**	**N**	**N (1, 3-7)**
	Other (Carotid, I/O)							

N= new indication; P= previously cleared by FDA

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization*
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	
Previous submission: K160807 - Affiniti	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: C9-4v Transducer for use with Sparq 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	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ	**N**	**N**	**N**		**N**	**N**	**N (1, 3-7)**
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	**N**	**N**	**N**		**N**	**N**	**N (1, 3-7)**
	Trans-vaginal	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Gynecological)	**P**	**P**	**P**		**P**	**P**	**P (1, 3-7)**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization*
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	
Previous submission: K160807 - Affiniti	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: L12-4 Transducer for use with Sparq 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	**N**	**N**	**N**		**N**	**N**	**N (1, 3-6)**
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	**P**	**P**	**P**		**P**	**P**	**P (1, 3-6, 8)**
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P (1, 3-6, 8)**
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P (1,3-6, 8)**
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P (1,3-6, 8)**
	Other (Specify)							
Cardiac	Cardiac Adult	**N**	**N**	**N**		**N**	**N**	**N (1,3,4,6, 8)**
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P (1,3-6, 8)**
	Other (Specify)							

N= new indication; P= previously cleared by FDA

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization*
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K160807 – Affiniti	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: L15-7io transducer for use with Sparq 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Musculo-skel (superficial)	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	**P**	**P**	**P**		**P**	**P**	**P** (1,3,4,5,7)
	Other (Carotid)							

N= new indication; P= previously cleared by FDA

***Other modes:** 1. Harmonics (Tissue & Contrast) 2. Tissue Doppler Imaging 3. iSCAN 4. X-Res	5. Angio 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: K123754 - CX50	

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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 FORM

510(k) Number: _____

Device name: S4-2 Transducer for use with Sparq 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**	**N**	**N**	**N**	**N (1, 3-5, 7)**
	Abdominal	**P**	**P**	**P**	**P**	**P**	**P**	**P (1, 3-5, 7)**
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Scrotum, Thyroid, Breast)	**N**	**N**	**N**	**N**	**N**	**N**	**N (1, 3-5, 7)**
	Neonatal Cephalic							
	Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P (1, 3-5, 7)**
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological) GYN	**N**	**N**	**N**	**N**	**N**	**N**	**N (1, 3-5, 7)**
Cardiac	Cardiac Adult	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-4)**
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**N**	**N**	**N**	**N**	**N**	**N**	**N (1, 3-5, 7)**
	Other (Specify)							

N= new indication; P= previously cleared by FDA

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization*
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	
Previous submission: K160807 - Affiniti	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: X7-2t Transducer for use with Sparq 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)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P (1,3,4)**
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization*
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K123754 - CX50	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

510(k) Summary of Safety and Effectiveness

CX50 and Sparq Diagnostic Ultrasound Systems

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

Date Prepared:	August 12, 2016	
Manufacturer:	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431 Establishment Registration Number: 3019216	
Primary Contact Person:	Maxs Newberry Regulatory Affairs Engineer Phone: 425-482-8810 Fax: 425-487-8666 E-mail: maxs.newberry@philips.com	
Device:	Common/usual name:	Diagnostic Ultrasound System and Transducers
	Proprietary name:	CX50 Diagnostic Ultrasound System, Sparq Diagnostic Ultrasound System
	Classification Regulation:	21CFR §892.1550, 21CFR §892.1560, 21CFR §892.1570
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	IYN (System, Imaging, Pulsed Doppler, Ultrasonic)
	Secondary Product Code:	IYO (System Imaging Pulsed Echo, Ultrasonic)
	Tertiary Product Code:	ITX (Transducer, Ultrasonic, Diagnostic)
Primary Predicate Device:	Trade Name:	CX50 Diagnostic Ultrasound System
	Manufacturer:	Philips Ultrasound, Inc.
	510(k) Clearance:	K123754 (December 21, 2012)
Reference device (if applicable):	Trade Name:	EPIQ 5 Diagnostic Ultrasound System EPIQ 7 Diagnostic Ultrasound System Affiniti 50 Diagnostic Ultrasound System Affiniti 70 Diagnostic Ultrasound System

Manufacturer: Philips Ultrasound, Inc.
510(k) Clearance: K160807 (April 6, 2016)

Device description: The modified CX50 and Sparq Diagnostic Ultrasound Systems are general purpose, software controlled, diagnostic ultrasound systems. Their function is to acquire ultrasound data and to display the data in various modes of operation.

The devices consist of two parts: the system console and the transducers. The system console contains the user interface, a display, system electronics and optional peripherals (ECG, printers). In addition to the physical knobs and buttons of the main control panel.

The CX50 Diagnostic Ultrasound System is a compact, AC or battery powered, 128 –channel, diagnostic ultrasound imaging system. It is housed in a portable, laptop-style chassis. An optional cart is available that allows the user to place the laptop on the cart for a more mobile application.

The Sparq Diagnostic Ultrasound System uses the same technology, but is a cart based mobile system. It provides a capacitive touch user interface and an articulating monitor arm.

The removable transducers are connected to the system using a standard technology, multi-pin connectors. The modified CX50 and Sparq systems use standard transducer technology, and support phased, linear, curved linear array, TEE, and non-imaging (pencil) probes.

Clinical data storage consists of a local repository as well as off-line image storage via the network, DVR, DVD, and USB storage devices. The images are stored in industry-standard formats (e.g. JPEG, AVI, DICOM) and are intended to be readable using industry-standard hardware and software. On-line review of the images is available. Secure access tools are provided to restrict and log access to the clinical data repository according to HIPAA.

The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The Doppler functions of the system process the Doppler shift frequencies from the echoes of moving targets such as blood to detect and graphically display the Doppler shifts of these tissues as flow.

The modified CX50 and Sparq systems give the operator the ability to measure anatomical structures and offer analysis packages that provide information used by competent healthcare professionals to make a diagnosis.

See Table 2 below for a comparison to the primary predicate device.

Table 2. Comparison of Modified CX50 and Sparq Features to the Predicate Device

Standard Feature	**CX50** **K123754** **(Predicate Device)**	**CX50 4.0** **(Modified Device)**	**Sparq 2.0** **(Modified Device)**
Indication for Use	Ophthalmic, Intracardiac echo, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Musculoskeletal, Gynecological, Cardiac Adult, Cardiac pediatric, Trans-Esophogeal. (Cardiac), Peripheral Vessel, Other (Carotid)	Same	Addition of trans-rectal indication
Transducers	• C5-1 • C8-5 • C9-3io • C9-3v • C10-3v • D2cwc • D5cwc • L10-4 lap • L12-3 • L12-5 50 • L15-7io • S5-1 • S8-3 • S12-4	Same with the following additional transducer with no new indications • S7-3t The new transducer introduces neither new indications for use nor new patient contact material.	Sparq shares the following three transducers with CX50 • C5-1 • L15-7io • X7-2t And adds the following additional transducers • C6-2 • C9-4v • L12-4 • S4-2 The new transducers introduce neither new indications for use nor new patient contact material. They are used on the currently

Table 2. Comparison of Modified CX50 and Sparq Features to the Predicate Device

Standard Feature	**CX50** **K123754** **(Predicate Device)**	**CX50 4.0** **(Modified Device)**	**Sparq 2.0** **(Modified Device)**
	• X7-2t		marketed EPIQ/Affiniti Diagnostic Ultrasound Systems (K160807)
Transducer Types	• Phased array • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • 3D Matrix Array	Same	Same * *Sparq does not have 3D Matrix Array transducers
Transducer Frequency	1.0 – 18.0 MHz	Same	Same
Acoustic Output Display & FDA Limits	IEC 62359 • ISPTA max=720 mw/cm2 • MI max =1.9 • MI display • TI display	Same	Same
Imaging Mode	• 2D Echo Imaging • M-mode Echo Imaging • PW Doppler Imaging • CW Doppler Imaging	Same	Same

Table 2. Comparison of Modified CX50 and Sparq Features to the Predicate Device

Standard Feature	**CX50** **K123754** **(Predicate Device)**	**CX50 4.0** **(Modified Device)**	**Sparq 2.0** **(Modified Device)**
	• 2D Color Doppler Imaging • Tissue Dopplwer Imaging and Harmonics (Tissue and Contrast) • Combination modes		
# Transmit Channels	128	Same	Same
# Receive Channels	256	Same	Same
510(k) Track	Track 3	Same	Same
System Characteristics	• Beamformer 128/128 • Portable Laptop that can be placed on mobile cart • Single LCD monitor	Same	Same technology, different form factor. Sparq is cart based, with an articulating monitor arm.
Product Safety Certification	CSA International ANSI/AAMI ES60601-1 IEC 60601-2-37	Same	Same
EMC Compliance	IEC 60601-1-2	Same	Same
Patient Contact Materials	All patient contact materials of the CX50 Ultrasound System and transducers are detailed in K123754.	Same No new patient contact materials	Same

Table 2. Comparison of Modified CX50 and Sparq Features to the Predicate Device			
Standard Feature	**CX50** **K123754** **(Predicate Device)**	**CX50 4.0** **(Modified Device)**	**Sparq 2.0** **(Modified Device)**
		comparing with the predicates.	No new patient contact materials comparing with the predicates.
Accessories	• Various hardcopy, recording and printing devices: report printer, DVD, USB • Biopsy guides • Footswitch	Same	Same

Indications for Use: The modified CX50 and Sparq Diagnostic Ultrasound Systems are intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical – mode), Pulse Wave Doppler, continuous Wave Doppler, color Doppler, tissue Doppler Imaging and Harmonics (Tissue and contrast) modes. The devices are indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic, Intracardiac echo, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Trans-rectal, Musculoskeletal, Gynecological, Cardiac Adult, Cardiac pediatric, Trans-Esophogeal. (Cardiac), Peripheral Vessel, Other (Carotid).

Technological characteristics: The modified CX50 and Sparq Diagnostic Ultrasound Systems, and the predicate CX50 Diagnostic Ultrasound System Cleared in K123754, are Track 3 systems and employ the same fundamental scientific technology. They are the same in materials, type of transducers, optimization, accessories and imaging modes. The primary differences between the modified CX50 and Sparq Diagnostic Ultrasound Systems, and the predicate CX50 Diagnostic Ultrasound System (K123754), are the addition of the S7-3t transducer to CX50, and the addition of the C6-2, C9-4v (new trans-rectal indication), L12-4 and S4-2 transducers to Sparq. Each of these transducers were cleared for use with the EPIQ and Affiniti Diagnostic Ultrasound Systems in K160807. The additional trans-rectal indication for use was cleared with on the C9-4v with ClearVue (K120321).

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the modified CX50 and Sparq Diagnostic Ultrasound Systems and demonstrates compliance with the following FDA recognized consensus standards:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2010
- ISO 10993: Biological evaluation of medical devices

The modified CX50 and Sparq Diagnostic Ultrasound Systems also comply with the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff – Information for manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008).

Non-Clinical verification testing has been performed to cover system level requirements and the risk control measures. Non-Clinical validation testing covered the intended use and commercial claims as well as usability testing with representative intended users.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the modified CX50 and Sparq Diagnostic Ultrasound Systems:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA ultrasound guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, modified CX50 and Sparq Diagnostic Ultrasound Systems are substantially equivalent to the predicate CX50 Diagnostic Ultrasound System in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The modified CX50 and Sparq Diagnostic Ultrasound Systems did not require clinical data since substantial equivalence to the primary currently marketed predicate CX50 Diagnostic Ultrasound System and reference predicate EPIQ Diagnostic Ultrasound System was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Substantial Equivalence Conclusion:

The modified CX50 and Sparq Diagnostic Ultrasound Systems are substantially equivalent to the currently marketed predicate device identified above:

- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems have the same gray-scale and Doppler capabilities.
- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems have acoustic output levels within the Track 3 FDA limits.
- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems are manufactured under equivalent quality systems.
- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems are manufactured of materials with equivalent bio safety. There is no new material or material change in application.
- The predicate device and the modified CX50 and Sparq Diagnostic Ultrasound Systems are designed and manufactured to the same electrical and physical safety standards.

514 Performance Standards

There are no Sec. 514 performance standards for the modified CX50 and Sparq systems.

Prescription Status The modified CX50 and Sparq Diagnostic Ultrasound Systems are prescription devices. The prescription device statement appears in the labeling.

Sterilization Sites Not applicable. No components are supplied sterile.

Track The modified CX50 and Sparq Diagnostic Ultrasound Systems are Track 3 systems.