

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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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,

Robert Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

For

Enclosure

Traditional 510(k)

CX50 and Sparq Diagnostic Ultrasound Systems Doc. ID: 243919 A Doc. Date: August 12, 2016 Page: 56 of 156

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) Subpart C)

Over-The-Counter Use (21 CFR 801

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Traditional 510(k)

CX50 and Sparq Diagnostic Ultrasound Systems

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Department of Health and Human Services Food and Drug Administration

Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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FORM FDA 3881 (8/14) Page 1 of 1

CX50 and Sparq Diagnostic Ultrasound Systems Doc. ID: 243919 A Doc. Date: August 12, 2016 Page: 58 of 156

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 Appli	ication	Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined	Other*	
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)	
Only)							See below		
Ophthalmic	Ophthalmic	P	P	P		P	P	P (1,4,6,7)	
	Fetal/Obstetric	P	P	P	P	P	P	P (1,3-8)	
	Abdominal	P	P	P	P	P	P	P (1,3-9)	
	Intraoperative	P	P	P		P	P	P (1,3,4,5,7)	
	(vascular/epicardial)								
	Intraoperative (Neuro)								
	Laparoscopic	P	P	P		P	P	P (1,3,4,5,7)	
Fetal	Pediatric	P	P	P		P	P	P (1,3-8)	
Imaging	Small Organ (thyroid,	P	P	P		P	P	P (1,3-8)	
& Other	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	P	P	P		P	P	P (1,3-8)	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Intra-luminal								
	Musculo-skel	P	P	P		P	P	P (1,3-8)	
	(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 Adult	P	P	P	P	P	P	P (1-4)	
Cardiac	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	Peripheral vessel	P	P	P	P	P	P	P (1,3-8)	
Vessel	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)

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number:	
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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 Appli	cation	Mo	ode o	f Operat	ion			
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
	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	_						
Fetal	Pediatric	P	P	P		P	P	P (1,3-9)
Imaging	Small Organ (thyroid, scrotum,							
& Other	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 Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1,3-8)
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				

(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

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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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 Appl	ication	Mo	ode o	f Operat	ion			
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	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							
Fetal	Pediatric	P	P	P		P	P	P (1,3-8)
Imaging	Small Organ (thyroid, scrotum,	P	P	P		P	P	P (1,3-8)
& Other	prostate, breast)							
	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 Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1,3-8)
Vessel	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 & 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

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Numbe	er:										
Device name:											
Intended Use:	Diagnostic ultrasound imaging or	fluid	flow	analysis	s of the h	uman body	as follows:				
Clinical Application Mode o				of Operation							
General	Specific	M	PWD	CWD	Color	Combined	Other*				
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)			
Only)											
Ophthalmic	Ophthalmic										
	Fetal/Obstetric										
	Abdominal	P	P	P		P	P	P (1,3,4,5,7)			
	Intraoperative	P	P	P		P	P	P (1,3,4,5,7)			
	(vascular/epicardial)										
	Intraoperative (Neuro)										
	Laparoscopic										
Fetal	Pediatric										
Imaging	Small Organ (thyroid, scrotum,	P	P	P		P	P	P (1,3,4,5,7)			
& Other	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 Adult										
Cardiac	Cardiac Pediatric										
	Trans-esoph. (Cardiac)										
	Other (Intracardiac)										
	Other (Fetal)										
Peripheral	Peripheral vessel	Î									
Vessel	Other (Carotid)										
N= new indica	ation; P= previously cleared by FD	A			l						
*Other me				5. Ar	ngio Imag	ring					
	ics (Tissue & Contrast)			6. 3D Imaging							
	Ooppler Imaging			7. SonoCT							
3. iSCAN				8. Biopsy guidance							
4. X-Res				9. Infertility monitoring of follicle development							

Previous submission: K123754 - CX50

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

Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD

Philips Ultrasound, Inc	Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems	Doc. ID: 243919 A Doc. Date: August 12, 2016 Page: 62 of 156
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

	Intended Use: D	Diagnostic ultrasound imaging or flu	id flo	ow aı	nalysis o	f the hun	nan body as fo	ollows:			
Clinical Application			Mode of Operation								
	General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify		
			_								
	Ophthalmic	Ophthalmic									
	Ophthalmic	Ophthalmic Fetal/Obstetric	P	P	P		P	P	P (1,3-8		
	Ophthalmic		P P	P P	P P		P P	P P	P (1,3-8 P (1,3-9		

C9-3v transducer for use with CX50 Diagnostic Ultrasound System

 Other (Gynecological)
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N= new indication; P= previously cleared by FDA

Intraoperative (Neuro)

Small Organ (thyroid, scrotum,

Musculo-skel (superficial)

Laparoscopic

prostate, breast)
Neonatal Cephalic

Pediatric

510(k) Number: Device name:

Fetal

Imaging

& Other

*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)

(CX50) and Spara Diagnostic	Philips Ultrasound, Inc	1 1 &	Doc. ID: 243919 A Doc. Date: August 12, 2016 Page: 63 of 156
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

C10-3v transducer for use with CX50 Diagnostic Ultrasound System

	Diagnostic ultrasound imaging or flu					iaii body as i	onows.	
Clinical Appl		Mo	de o	f Operat	ion			
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
	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							
Fetal	Pediatric							
Imaging & Other	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							

Vessel Other (Specify)
N= new indication; P= previously cleared by FDA

Trans-esoph. (non-Card.)

Musculo-skel (conventional) Musculo-skel (superficial) Other (Gynecological)

Intra-luminal

Cardiac Adult

Cardiac Pediatric
Trans-esoph. (Cardiac)
Other (Intracardiac)
Other (Fetal)
Peripheral vessel

510(k) Number:

Device name:

Cardiac

Peripheral

*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+Colo	r, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: K123754 - CX50	

P P

P

P (1,3-9)

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510(k) Number: _____

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name: Intended Use: I	D2cwc transducer for use with Diagnostic ultrasound imaging or float						ollows.	
Clinical Appl	<u> </u>	-		f Operat		idii oody as i	onows.	
General (Track I Only)	Specific (Tracks I & III)	В	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)							
Cardiac	Other (Gynecological) Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Intracardiac) Other (Fetal)				P P			
Peripheral Vessel	Peripheral vessel Other (Carotid)	F						

N= new indication; P= previously cleared by FDA

	T is a second of the second of	
* Other modes:		
Combined modes:		
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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number	:								
Device name:	D5cwc transducer for use with								
Intended Use: I	Diagnostic ultrasound imaging or fl	uid fl	ow a	nalysis c	of the hun	nan body as f	follows:		
Clinical Appli		Mo	ode o	f Operat	ion				
General	Specific	В	M	PWD	CWD	Color	Combined	Other*	
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)	
Only)							See below		
Ophthalmic	Ophthalmic								
	Fetal/Obstetric								
	Abdominal								
	Intraoperative								
	(vascular/epicardial)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging	Small Organ (thyroid, scrotum,								
& Other	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 Adult								
Cardiac	Cardiac Pediatric				P			P (1-7)	
	Trans-esoph. (Cardiac)	Î							
	Other (Intracardiac)								
	Other (Fetal)								
Peripheral	Peripheral vessel				P				
Vessel	Other (Carotid)				P				
N= new indicat	ion; P= previously cleared by FDA		•	•			•	•	
*Other mo				5. Angi	io Imagin	g			
1. Harmonio	es (Tissue & Contrast)			6. 3D I	maging				
2. Tissue Do	oppler Imaging			7. Sono					
3. iSCAN				8. Biopsy guidance					
4. X-Res							llicle develop	ment	
Combined mo	des: B+PWD, B+Color, B+M, B+N	M+Co	olor, l	B+Color	+PWD, I	B+CWD, B+	Color+CWD		

(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)

Previous submission: K123754 - CX50

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Numbe											
	L10-4lap transducer for use w										
Intended Use:	Diagnostic ultrasound imaging o	r fluid	l flow	v analysi	is of the l	numan body	as follows:				
Clinical App		Mo	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined	Other*			
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)			
Only)											
Ophthalmic	Ophthalmic										
	Fetal/Obstetric										
	Abdominal										
	Intraoperative										
	(vascular/epicardial)										
	Intraoperative (Neuro)										
	Laparoscopic	P	P	P		P	P	P (1,3,4,5,7)			
Fetal	Pediatric										
Imaging	Small Organ (thyroid,										
& Other	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 Adult										
Cardiac	Cardiac Pediatric										
	Trans-esoph. (Cardiac)										
	Other (Intracardiac echo)										
	Other (Fetal)										
Peripheral	Peripheral vessel										
Vessel	Other (Specify)										
N= new indica	ation; P= previously cleared by Fl	DΑ									
*Other me				5. Angi	io Imagin	g					
1. Harmon	ics (Tissue & Contrast)			6. 3D I	maging						
2. Tissue D	Doppler Imaging			7. Sono							
3. iSCAN					sy guidar						
4. X-Res							ollicle develo				
	odes: B+PWD, B+Color, B+M, I	3+M+	-Colo	or, B+Co	lor+PWI	D, B+CWD,	B+Color+CV	VD			
Previous sub	mission: 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

510(k) Number:

Device name:

Fetal

Imaging

& Other

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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P (1,3-8)

P (1,3-8)

P

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

L12-3 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: I	Diagnostic ultrasound imaging or fl	uid fl	ow a	nalysis o	f the hur	nan body as f	ollows:	
Clinical Appl	ication	Mo	ode o	f Operat	ion			
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1,3-8)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							

P P

P

Neonatal Cephalic P P **P** (1-8) P P P Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Intra-luminal **P** (1,3-8) Musculo-skel (conventional) P P P P P P Musculo-skel (superficial) P P P P **P** (1,3-8)

P

P

P

P

P

Cardiac Adult Cardiac Cardiac Pediatric Trans-esoph. (Cardiac) Other (Intracardiac) Other (Fetal) Peripheral vessel Peripheral P P P P **P** (1,3-8) Vessel Other (Carotid) P P P P P (1,3-8)

N= new indication; P= previously cleared by FDA

Other (Gynecological)

Laparoscopic

prostate, breast)

Small Organ (thyroid, scrotum,

Pediatric

*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	or, 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)

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number:	
Device name: L12-5 50 transducer for use with CX50 Diagnostic Ultrasou	nd System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the hum	an hody as follows:

Clinical Application Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	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						_	
Fetal	Pediatric	P	P	P		P	P	P (1,4,6,7,8)
Imaging & Other	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)	<u> </u>	1	1		1	1	1 (1,4,0,7,0)
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac echo)							
	Other (Fetal)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1,4,6,7,8)
Vessel	Other (Carotid)	P	P	P		P	P	P (1,4,6,7,8)

N= new indication; P= previously cleared by $FD\overline{A}$

*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+Colo	r, 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

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number:		
Device name:	L15-7io transducer for use with CX50 Diagnostic Ultrasound System	
Intended Use: Di	agnostic ultrasound imaging or fluid flow analysis of the human body as follows:	

Clinical App	lication	ation Mode of Operation						
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I	(Tracks I & III)	ı				Doppler	(Specify)	(Specify)
Only)								
Ophthalmic	Ophthalmic							
	Fetal/Obstetric							
	Abdominal							
	Intraoperative	P	P	P		P	P	P (1,3,4,5,7)
	(vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
Fetal	Pediatric							
Imaging	Small Organ (thyroid,	P	P	P		P	P	P (1,3,4,5,7)
& Other	scrotum, prostate, breast)							
	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 Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1,3,4,5,7)
Vessel	Other (Carotid)							,

N= new indication; P= previously cleared by \overline{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+Colo	r, 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

510(k) Number:

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name: Intended Use: 1	S12-4 transducer for use with Oiagnostic ultrasound imaging or flu						follows:	
Clinical Appl				f Operat				
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	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							
Fetal	Pediatric	P	P	P		P	P	P (1-4,6)
Imaging & Other	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 (Carotid) N= new indication; P= previously cleared by FDA

Other (Gynecological)

Trans-esoph. (Cardiac) Other (Intracardiac) Other (Fetal) Peripheral vessel

Cardiac Adult

Cardiac Pediatric

Cardiac

Peripheral

Vessel

*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+Colo	r, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: K123754 - CX50	

P P

P

P

P

P

P

P

P

P (1-4,6)

P (1-4,6)

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

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

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				ion				
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	P	P	P		P	P	P (1,4,6,7)
	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intraoperative (Neuro)							
Fetal	Laparoscopic Pediatric							
Imaging & Other	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)	-		D	D			
Candiaa	Cardiac Adult Cardiac Pediatric	P P	P	P P	P	P P	P P	P (1.7)
Cardiac		ľ	P	P	P	ľ	P	P (1-7)
	Trans-esoph. (Cardiac) Other (Intracardiac)	\vdash						
	Other (Fetal)							
Peripheral	Peripheral vessel							
Vessel	Other (Carotid)							
V C33C1	Other (Carotta)						1	

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

510(k) Number:

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name: Intended Use: I	S7-3t transducer for use with C Diagnostic ultrasound imaging or flu						follows:			
Clinical Appli	<u> </u>			f Operat		· · · · · ·				
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)		
Ophthalmic	Ophthalmic									
	Fetal/Obstetric									
	Abdominal	1_								
	Intraoperative									
	(vascular/epicardial)									
	Intraoperative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging	Small Organ (thyroid, scrotum,					·				
& Other	prostate, breast)					<u> </u>				
	Neonatal Cephalic	L				<u> </u>	<u> </u>			
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral						T			
	Trans-esoph. (non-Card.)									
	Intra-luminal						T			
	Musculo-skel (conventional)									
	Musculo-skel (superficial)									
	Other (Gynecological)									
	Cardiac Adult	Т								
Cardiac	Cardiac Pediatric						T			
	Trans-esoph. (Cardiac)	Р	Р	Р	Р	Р	Р	P (1-5)		
	Other (Intracardiac)									
	Other (Fetal)									
Peripheral	Peripheral vessel	Τ								
Vessel	Other (Specify)						T			
N= new indicat	ion; P= previously cleared by FDA	-		•	<u> </u>		<u>, </u>			
*Other mo					io Imagin	ıg				
1. Harmonio	cs (Tissue & Contrast)			6. 3D I						
	oppler Imaging			7. SonoCT						
3. iSCAN					sy guidar					
4. X-Res			9. Infertility monitoring of follicle development							

Previous submission: S7-3t cleared in K160807 – EPIQ
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Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD

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

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number:	
Device name:	S8-3 transducer for use with CX50 Diagnostic Ultrasound System
Intended Use: Di	agnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Mode of O				f Operat	peration					
General (Track I Only)	Specific (Tracks I & III)							Other* (Specify)		
Ophthalmic	Ophthalmic									
	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									
Fetal	Pediatric	P	P	P		P	P	P (1-4,6)		
Imaging & Other	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 Adult	P	P	P	P	P	P	P (1-4,6)		
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P (1-4,6)		
	Trans-esoph. (Cardiac)									
	Other (Intracardiac)									
	Other (Fetal)									
Peripheral	Peripheral vessel									
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

510(k) Number:

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name:	X7-2t transducer for use with C							
<u> </u>	Diagnostic ultrasound imaging or flu			•		nan body as f	ollows:	
Clinical Appli				of Operat			1	т
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)
Only)		丄	<u> </u>					
Ophthalmic	Ophthalmic	上	Щ.	<u> </u>			<u> </u>	
	Fetal/Obstetric							
1	Abdominal							
·	Intraoperative							
·	(vascular/epicardial)							
	Intraoperative (Neuro)	L						
	Laparoscopic	L						
Fetal	Pediatric			<u> </u>			T	
Imaging	Small Organ (thyroid, scrotum,	Γ						
& Other	prostate, breast)	L	<u> </u>					
	Neonatal Cephalic	L						
	Adult Cephalic	L						
	Trans-rectal							
1	Trans-vaginal						T	
 	Trans-urethral	Γ_						
	Trans-esoph. (non-Card.)							
	Intra-luminal	Г						
	Musculo-skel (conventional)							
 	Musculo-skel (superficial)							
	Other (Gynecological)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric						1	
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P (1-6)
	Other (Intracardiac)	1					1	
1	Other (Fetal)						1	
Peripheral	Peripheral vessel	\top						
Vessel	Other (Carotid)							
N= new indicat	ion; P= previously cleared by FDA			<u></u>			1	
*Other mod			\Box	5. Angi	io Imagin	າຍ		
	es (Tissue & Contrast)				maging	8		
	oppler Imaging			7. Sono				
3. iSCAN				8. Biop	sy guidar	nce		
1 Y Pec							illicle develon	ment

Previous submission: K123754 - CX50
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Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD

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

510(k) Number:

Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name:	St. Jude Medical ViewFlex Xtr Diagnostic ultrasound imaging or flu							und System			
Clinical Appli			Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	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) Other (Fetal)	P	P	P	P	P	P	P (1-7)			
Peripheral	Peripheral vessel										
Vessel	Other (Carotid)										
	ion; 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					ment						
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD											

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

Prescription Use (Per 21 CFR 801.109)

Previous submission: K123754 - CX50

Traditional 510(k)

CX50 and Sparq Diagnostic Ultrasound Systems Doc. ID: 243919 A Doc. Date: August 12, 2016 Page: 76 of 156

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) Subpart C)

Over-The-Counter Use (21 CFR 801

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Traditional 510(k)

CX50 and Sparq Diagnostic Ultrasound Systems Doc. ID: 243919 A Doc. Date: August 12, 2016 Page: 77 of 156

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Department of Health and Human Services Food and Drug Administration

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PSC

510(k) Number:

3. iScan4. X-Res

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name: Philips Ultrasound, Inc. Sparq Diagnostic Ultrasound System								
Intended Use: 1	Diagnostic ultrasound imaging	g or f	luid	flow ana	lysis of t	he human be	ody as follows	:
Clinical Appl	ication	Mo	ode o	f Operat	ion			
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)
Only)							See below	
Ophthalmic	Ophthalmic	N	N	N		N	N	N (1,3-7)
	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							
Fetal	Pediatric							
Imaging	Small Organ (thyroid,	N	N	N	N	N	N	N (1,3-8)
& Other	scrotum, prostate, breast)							
	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	N	N	N		N	N	N (1,3-7, 8)
	(conventional)							
	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 Adult	N	N	N	N	N	N	N (1-5, 7, 8)
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N (1,3,4)
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N	N	N	N	N (1,3-7, 8)
Vessel	Other (Specify)							
N= new indication	on; P= previously cleared by FDA	1			_			
Other Modes			5.	Angio In	naging			
	Γissue or Contrast)			SonoCT				
2. Tissue Dopp	oler Imaging		7.	Biopsy (Guidance			

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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

8. Needle Visualization*

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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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 Appl	ication	Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
	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	\vdash						
Fetal	Pediatric	P	P	P		P	P	P (1, 3-7)
Imaging & Other	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 Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1, 3-7)
Vessel	Other (Carotid)							

N= new indication; P= previously cleared by FDA

*Other modes:	5. Angio Imaging					
1. Harmonics (Tissue & Contrast)	6. SonoCT					
2. Tissue Doppler Imaging	7. Biopsy guidance					
3. iSCAN	8. Infertility monitoring of follicle development					
4. X-Res						
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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4. X-Res

Previous submission: K160807 - Affiniti

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

General	tion	Mod	e of Or	peration				
(Track I Only)	Specific (Tracks I & III)	B M PWD CWD Color Combined Doppler (Specify)						
Ophthalmic	Ophthalmic							
	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							
Fetal Imaging	Pediatric							
& Other	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 Adult	N	N	N		N	N	N (1-4, 7)
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N		N	N	N (1, 3-7)
Vessel	Other (Carotid, I/O)							
N= new indication	n; P= previously cleared by FDA	_	•	•		•		
Other Modes				Angio Ima	aging			
1. Harmonic (Ti	issue or Contrast)		6.	SonoCT				
2. Tissue Doppl3. iScan	er Imaging			Biopsy G	uidance isualizatio			

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Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

510(k) Number:

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device name: Intended Use: Dia	C9-4v Transducer for use w agnostic ultrasound imaging or								
	nical Application						nultaneous B-n	node)	
General (Track I Only)	Specific (Tracks I & III)	В							
Ophthalmic	Ophthalmic							` • •	
-	Fetal	P	P	P		P	P	P (1, 3-7)	
	Abdominal							- (-,- ,)	
	Intra-operative (Abdominal, vascular)								
	Intra-operative (Neuro.)								
	Laparoscopic								
Fetal Imaging	Pediatric								
& Other	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 Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal								
	(Cardiac)								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								
	P= previously cleared by FDA								
Other Modes 1. Harmonic (Tis 2. Tissue Dopple 3. iScan 4. X-Res	r Imaging			6. Sono C 7. Biops 8. Needl	y Guidanc e Visualiz				
Combined modes	s: Duplex = $2D + Doppler$; Triplex	x = 2D	+ Dop	pler + Co	olor, Dual				
Previous submis	ssion: K160807 - Affiniti								

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Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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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 Appli	cation			f Operat		•		
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	N	N	N		N	N	N (1, 3-6)
	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1, 3-6, 8)
	Intra-operative (vascular/epicardial) Intra-operative (Neuro)							
	Laparoscopic							
Fetal	Pediatric							
Imaging & Other	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 Adult	N	N	N		N	N	N (1,3,4,6, 8)
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1,3-6, 8)
Vessel	Other (Specify)							

N= new indication; P= previously cleared by FDA

<u> </u>					
Other Modes	5. Angio Imaging				
Harmonic (Tissue or Contrast)	6. SonoCT				
2. Tissue Doppler Imaging	7. Biopsy Guidance				
3. iScan	8. Needle Visualization*				
4. X-Res					
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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Traditional 510(k)
CX50 and Sparq Diagnostic
Ultrasound Systems

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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				

Clinical App	lication	Mode of Operation						
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)
Only)								
Ophthalmic	Ophthalmic							
	Fetal/Obstetric							
	Abdominal							
	Intraoperative							
	(vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
Fetal	Pediatric							
Imaging	Small Organ (thyroid,	P	P	P		P	P	P (1,3,4,5,7)
& Other	scrotum, prostate, breast)							
	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 Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)					_		
	Other (Fetal)							
Peripheral	Peripheral vessel	P	P	P		P	P	P (1,3,4,5,7)
Vessel	Other (Carotid)							,

N= new indication: P= previously cleared by FDA

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*Other modes:	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. SonoCT
2. Tissue Doppler Imaging	7. Biopsy guidance
3. iSCAN	8. Infertility monitoring of follicle development
4. X-Res	
Combined modes: B+PWD, B+Color, B+M, B+M+Colo	or, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: K123754 - CX50	

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Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _								
Device name:	S4-2 Transducer for use wit						0.11	
	agnostic ultrasound imaging or			· · · · ·		nan body as	follows:	
Clinical Applica		-	1	peration			I	
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)	-				Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	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							
Fetal Imaging	Pediatric							
& Other	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 Adult	P	P	P	P	P	P	P (1-4)
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N	N	N	N	N (1, 3-5, 7)
Vessel	Other (Specify)							
N= new indicatio	n; P= previously cleared by FI)A		•		'		
Other Modes 1. Harmonic (Tis 2. Tissue Dopple 3. iScan 4. X-Res	sue or Contrast) r Imaging			8. Needle	T y Guidance e Visualiza	ntion*		
Combined mode	es: Duplex = $2D + Doppler$; Tr	riplex =	= 2D +	- Dopple	r + Color	, Dual		
Previous submis	ssion: K160807 - Affiniti							

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound Systems

Device name: X7-2t Transducer for use with Sparq Diagnostic Ultrasound System	510(k) Number	r:							
Clinical Application									
Specific (Track I (Intended Use: 1	Diagnostic ultrasound imaging or flu	uid fl	ow a	nalysis o	f the hun	nan body as f	follows:	
CTrack I	Clinical Appl	Node of Operation							
Only Ophthalmic Ophthalmi	General Specific I			M	PWD	CWD	Color	Combined	Other*
Ophthalmic Fetal/Obstetric Abdominal Intra-operative (vascular/epicardial) Intra-operative (vascular/epicardial) Intra-operative (Neuro) Laparoscopic Intra-operative (Neuro) Laparoscopic Intra-operative (Neuro) Intra-operative (Ne	(Track I	(Tracks I & III)					Doppler	(Specify)	(Specify)
Fetal/Obstetric	Only)								
Abdominal Intra-operative (vascular/epicardial) Intra-operative (Neuro) Laparoscopic Pediatric Imaging & Other Small Organ (thyroid, scrotum, prostate, breast) Neonatal Cephalic Intra-operative (Neuro) Intr	Ophthalmic	Ophthalmic							
Intra-operative (vascular/epicardial)		Fetal/Obstetric	Т						
(vascular/epicardial)		Abdominal							
Intra-operative (Neuro)		Intra-operative							
Laparoscopic		(vascular/epicardial)							
Petal		Intra-operative (Neuro)							
Small Organ (thyroid, scrotum, prostate, breast) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Intra-luminal Musculo-skel (conventional) Musculo-skel (superficial) Other (Specify) Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) P P P P P P P P P P P P P P P P P P		Laparoscopic							
& Other prostate, breast)	Fetal	Pediatric							
Neonatal Cephalic	Imaging	Small Organ (thyroid, scrotum,							
Adult Cephalic	& Other								
Trans-rectal									
Trans-vaginal		Adult Cephalic							
Trans-urethral									
Trans-esoph. (non-Card.)		Trans-vaginal							
Intra-luminal Musculo-skel (conventional) Musculo-skel (superficial) Other (Specify) Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify) Peripheral Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Intra-luminal Musculo-skel (conventional) P P P P P P P P P P P P P P P P P P P		Trans-urethral							
Musculo-skel (conventional) Musculo-skel (superficial) Other (Specify) Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify) Peripheral Peripheral Peripheral vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Musculo-skel (conventional) P P P P P P P P P P P P P P P P P P P		Trans-esoph. (non-Card.)							
Musculo-skel (superficial) Other (Specify) Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify) Peripheral Vessel Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Musculo-skel (superficial) P P P P P P P P P P P P P P P P P P P		Intra-luminal							
Other (Specify) Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify) Peripheral Vessel Other (Specify) Peripheral vessel Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Other (Specify) Section 1 Angio Imaging Cardiac Adult Angio Imaging Cardiac Adult Section 2 Angio Imaging Cardiac Adult Section 3 Angio Imaging Cardiac Adult Section 3 Cardiac Adult Section 3 Cardiac Adult Cardiac Adult Section 3 Cardiac Adult Section 4 Cardiac Adult Section 3 Cardiac Adult Section 3 Cardiac Adult Section 4 Ca		Musculo-skel (conventional)							
Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify) Peripheral Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Cardiac Adult PP P P P P P P P P P P P P P P P P P P									
Cardiac Pediatric Trans-esoph. (Cardiac) PPPPPPPPPPPPPP(1,3,4) Other (Specify) Peripheral Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Cardiac Pediatric PPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPP		Other (Specify)							
Trans-esoph. (Cardiac) Other (Specify) Peripheral Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Trans-esoph. (Cardiac) P P P P P P P P P P P P P P P P P P P		Cardiac Adult							
Other (Specify) Peripheral Peripheral vessel Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Other (Specify) 5. Angio Imaging 6. SonoCT 7. Biopsy Guidance	Cardiac	Cardiac Pediatric							
Peripheral Peripheral vessel Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging Total Contract of the peripheral vessel 5. Angio Imaging 6. SonoCT 7. Biopsy Guidance		Trans-esoph. (Cardiac)	P	P	P	P	P	P	P (1,3,4)
Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 5. Angio Imaging 6. SonoCT 7. Biopsy Guidance		Other (Specify)							
Vessel Other (Specify) N= new indication; P= previously cleared by FDA Other Modes 1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 5. Angio Imaging 6. SonoCT 7. Biopsy Guidance	Peripheral	Peripheral vessel							
Other Modes 5. Angio Imaging 1. Harmonic (Tissue or Contrast) 6. SonoCT 2. Tissue Doppler Imaging 7. Biopsy Guidance	Vessel	Other (Specify)							
Other Modes 5. Angio Imaging 1. Harmonic (Tissue or Contrast) 6. SonoCT 2. Tissue Doppler Imaging 7. Biopsy Guidance	N= new indicat	tion; P= previously cleared by FDA	•						
 Harmonic (Tissue or Contrast) Tissue Doppler Imaging Biopsy Guidance 					5. Angio	Imaging			
					6. Sono	CT			
5. 1Scan 8. Needle Visualization [*]		oler Imaging							
4. X-Res					8. Need	ie Visualii	zation*		

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Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD

Previous submission: K123754 - CX50

Traditional 510(k)

CX50 and Sparq Diagnostic Ultrasound Systems

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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

Maxs Newberry

Regulatory Affairs Engineer Person:

> Phone: 425-482-8810 Fax: 425-487-8666

E-mail: maxs.newberry@philips.com

Common/usual name: **Device:** Diagnostic Ultrasound System and Transducers

> CX50 Diagnostic Ultrasound System, Sparq Proprietary name:

> > Diagnostic Ultrasound System

21CFR §892.1550, 21CFR §892.1560, 21CFR Classification Regulation:

§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

Traditional 510(k) CX50 and Sparq Diagnostic Ultrasound Systems

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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.

Philips Ultrasound, Inc	Traditional 510(k)	Doc. ID: 243919 A
	CX50 and Sparq Diagnostic Ultrasound Systems	Doc. Date: August 12, 2016 Page: 47 of 156

Standard Feature	CX50	CX50 4.0	Sparq 2.0	
reature	K123754	(Modified	(Modified Device)	
	(Predicate Device)	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	Same with the following	Sparq shares the following three	
	• C8-5	additional	transducers with CX50	
	• C9-3io	transducer with no new	• C5-1	
	• C9-3v	indications	• L15-7io	
	• C10-3v	• S7-3t	• X7-2t	
	• D2cwc	The new transducer	And adds the following additional transducers	
	• D5cwc	introduces neither new	• C6-2	
	• L10-4 lap	indications for		
	• L12-3	use nor new patient contact	• C9-4v	
	• L12-5 50	material.	• L12-4	
	• L15-7io		• S4-2	
	• S5-1		The new transducers introduce neither new	
	• S8-3		indications for use nor new patient contact	
	• S12-4		material. They are used on the currently	

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

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Standard Feature	CX50	CX50 4.0	Sparq 2.0 (Modified Device)	
reature	K123754	(Modified Device)		
	(Predicate Device)	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	Same	
		No new patient contact materials		

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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).

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Summary of Non-Data:

Non-clinical performance testing has been performed on the modified CX50 and Clinical Performance 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.

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Performance Data:

Summary of Clinical 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.

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Prescription Status	The modified CX50 and Sparq Diagnostic Ultrasound Systems are prescription devices. The prescription device statement appears in the labeling.				
Sterilization Sites	Not applic	cable. No components are supplied s	sterile.		

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