3.2 Summary of Safety and Effectiveness

JUL 11 2008

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 C.F.R. §807.92.

The submitter of this premarket notification is:

Rob Butler
Manager, Regulatory Affairs
Philips Ultrasound, Inc.
3000 Minuteman Road
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This summary was prepared on May 8, 2008.

The proprietary name of the device is the CX50 Diagnostic Ultrasound System. In combination with transducers – S5-1, X7-2t, D2CWC – the system is commonly known as a diagnostic ultrasound system and transducers.

These devices are classified as follows:

90IYN	Ultrasonic Pulsed Doppler Imaging System
90IYO	Ultrasonic Pulsed Echo Imaging System
90ITX	Diagnostic Ultrasound Transducer

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

The CX50 is a compact diagnostic ultrasound device. It consists of a system console containing the power supply and electronic circuitry required to generate the image, a display screen, and a connection to the separate transducers. It is substantially equivalent to the currently marketed Philips HD11 ultrasound system and transducers cleared in K043535 and the General Electric Vivid-i ultrasound system and transducers cleared in K061525.

The CX50 system and transducers function in a manner identical to currently marketed Philips ultrasound systems and transducers. 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 differing acoustic properties of the tissues in the body reflect some of the transmitted energy back to the transducer, where it is converted back to electrical signals and sent back to the system. In the system, advanced signal processing technologies convert the returned signals into images of the tissues. The Doppler functions of this 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 CX50 is intended for diagnostic ultrasound imaging and fluid flow analysis.

The CX50 is substantially equivalent in safety and effectiveness to the predicates identified above:

- Both the predicate devices and the CX50 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate devices and the CX50 have the same gray-scale and Doppler capabilities.
- Both the predicate devices and the CX50 use essentially the same technologies for imaging, Doppler functions and signal processing.
- Both the predicate devices and the CX50 have acoustic output levels below the Track 3 FDA limits.
- Both the predicate devices and the CX50 are manufactured under equivalent quality systems.
- Both the predicate devices and the CX50 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate devices and CX50 are designed and manufactured to the same electrical and physical safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2008

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

Re: K081802
Trade/Device Name: CX50 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: ITX, IYN, and IYO
Dated: June 25, 2008
Received: June 26, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CX50 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

S5-1
X7-2t
D2cwc

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

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

Enclosure(s)

4.3.2 Indications for Use Tables

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)	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 (Gynecological)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

* Other modes: Harmonics (Tissue & Contrast), Tissue Doppler Imaging
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: No previous 510(k)s are associated with this product

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

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

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081802

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)	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 (Gynecological)							
Cardiac	Cardiac Adult	**P**	**P**	**P**	**P**	**P**	**P**	**P**
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

* Other modes: Harmonics (Tissue & Contrast), Tissue Doppler Imaging
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: K042540 – use of S5-1 transducer with Philips iU22 Ultrasound System

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

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081802

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							
	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 (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

* Other modes: Harmonics (Tissue & Contrast), Tissue Doppler Imaging
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD
Previous submission: K043535 – use of X7-2t transducer with Philips HD11 Ultrasound System (transducer referred to as "T6H" in that submission)

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

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081802

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							
	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 (Gynecological)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

* Other modes:
Combined modes:
Previous submission: K043535 – use of D2cwc transducer with Philips HD11 Ultrasound System

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

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081802