K042540

OCT 4 - 2004

510(k) Summary of Safety and Effectiveness

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

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

Philips Ultrasound
22100 Bothell Everett Highway
Telephone: (425) 487-7312
Facsimile: (425) 487-8666
E-mail: Lynn.harmer@philips.com

Contact Person: Lynn Harmer

Date prepared: 21 July 2004

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic ultrasound system with accessories
Proprietary Name: iU22 ultrasound system

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

3) Substantially Equivalent Devices

Philips Ultrasound believes that the iU22 system and transducers are substantially equivalent to the following currently marketed devices:

QLAB (K040227;) LVAnalysis (K022824;) and M2424 (K022303)

4) Device Description & Technical Comparison to Predicate Devices

The iU22 system and transducer(s) function in a manner identical to all diagnostic 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 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 iU22 system gives the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

5) Intended Use

The iU22 system and transducers are intended for diagnostic ultrasound imaging and fluid flow analysis of the human body.

6) Conclusion

The iU22 system and transducers are substantially equivalent in safety and effectiveness to the predicate systems and transducers listed in item 3 above.

- The systems are intended for diagnostic ultrasound imaging and fluid flow analysis.
- The systems have the same gray-scale and Doppler capabilities.
- The systems use essentially the same technologies for imaging, Doppler functions and signal processing.
- The systems have acoustic output levels below the applicable FDA limits.
- The systems are manufactured of materials with materials that have been evaluated and found to be safe for its application.
- The systems are designed and manufactured to applicable electrical and physical safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

Phillips Ultrasound, Inc.
% Ms. Michelle S. Lee
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K042540
Trade Name: iU22 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: September 17, 2004
Received: September 20, 2004

Dear Ms. Lee:

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 iU22 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

X3-1
S5-1

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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **iU22 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	P	P	P		P	Notes 1, 3	Notes 5, 6, 8,10,12, 13
Fetal Imaging & Other	Fetal	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 7, 8, 10, 12, 13
	Abdominal	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 7, 8, 10, 11, 12, 13
	Intra-operative *(Abdominal, Cardiac*, Spine, Vascular)*	P/N*	P/N*	P/N*		P/N*	Notes 1, 3	Notes 5, 6, 8,10,12, 13
	Intra-operative (Neuro.)	P	P	P		P	Notes 1, 3	Notes 3, 5, 6, 10, 12, 13
	Laparoscopic	P	P	P		P	Notes 1, 3	Notes 8, 10, 12, 13
	Pediatric	P	P	P		P	Notes 1, 2, 3	Note 5, 6, 8, 9, 10, 12, 13
	Small Organ *(breast, thyroid, testicle)*	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 8, 10, 11, 12, 13
	Neonatal Cephalic	P	P	P		P	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Adult Cephalic	P	P	P	P	P	Notes 1, 3, 4	Notes 10, 13
	Trans-rectal	P	P	P		P	Notes 1, 3	Notes 5,6,10,11,12, 13
	Trans-vaginal	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 7,10, 11,12, 13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 8,10, 12,13
	Musculo-skel. (Superficial)	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12,13
	Intra-luminal							
	Other: Urology	P	P	P		P	Notes 1, 3	Notes 5, 10, 12
Cardiac	Cardiac Adult	P	P	P	P	P	Notes 1,2,3,4	Notes 10, 11, 12, 13
	Cardiac Pediatric	P	P	P	P	P	Notes 1,2,3,4	Notes 10, 11, 12, 13
	Trans-esophageal (Cardiac)	P	P	P	P	P	Notes 1,2,3,4	Note 10
	Other *(Fetal Echo)*	P	P	P	P	P	Notes 1,2,3,4	Notes 5,10, 12, 13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Notes 1, 2, 3	Notes 2, 3, 5, 6, 7, 8, 10, 12, 13
	Cerebral Vascular	P	P	P		P	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Addition of intraoperative (cardiac)
**Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Prescription Use (Per 21 CRF 801.109)
Concurrence of CDRH, Office of Device Evaluation (ODE)

David A Lagorm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042540

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **iU22 Ultrasound System**
Transducer: **X3-1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Abdominal	P	P	P		P	Notes 1,3	Notes 5, 6, 8, 10, 12, 13
	Intra-operative (cardiac)	N	N	N		N	Notes 1,2,3	Notes 10, 11, 12, 13
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Notes 10, 11, 12, 13
	Cardiac Pediatric	N	N	N		N	Notes 1, 2, 3	Notes 10, 11, 12, 13
	Trans-esophageal (Cardiac)							
	Fetal Echo	P	P	P		P	Notes 1, 2, 3	Notes 5, 10, 12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Prescription Use (Per 21 CRF 801.109)
Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042540

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **iU22 Ultrasound System**
Transducer: **S5-1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (cardiac)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult	E	E	E	E	E	Notes 1, 2 3, 4	Notes 10, 11, 13
	Cardiac Pediatric	E	E	E	E	E	Notes 1, 2 3, 4	Notes 10, 11, 13
	Trans-esophageal (Cardiac)							
	Fetal Echo							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
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Note 13: XRES

Prescription Use (Per 21 CRF 801.109)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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