K014191

JAN 0 7 2002

3.2 Summary of Safety and Effectiveness

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:

Steve Singlar
Regulatory Engineer
Philips Medical Systems
Philips Ultrasound Division
3000 Minuteman Road, MS 0135
Andover, MA 01810
Tel: (978) 659-2101
Fax: (978) 975-7324

This summary was prepared on November 19, 2001.

The proprietary name of the device is the M2540 Diagnostic Ultrasound System. In combination with the new transducers - 21373B, 21422A, 21425A, 21426A, 21475A - are 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 M2540 is a 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 ultrasound systems including the M2410 Ultrasound system with transducers.

The 21422A, 21425A, 21446A, 21475A transducers are substantially equivalent to the Philips sector, linear and endo-cavity ultrasound transducers.

The M2540 system and transducers function in a manner identical to all 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 M2540 is intended for diagnostic ultrasound imaging and fluid flow analysis.

The M2540 is substantially equivalent in safety and effectiveness to the predicates identified above:

- Both the predicate device and the M2540 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate device and the M2540 have the same gray-scale and Doppler capabilities.
- Both the predicate device and the M2540 use essentially the same technologies for imaging, Doppler functions and signal processing.
- Both the predicate device and the M2540 have acoustic output levels below the Track 3 FDA limits.
- Both the predicate device and the M2540 are manufactured under equivalent quality systems.
- Both the predicate device and the M2540 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate device and M2540 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

JAN 0 7 2002

Phillips Medical Systems
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K014191
Trade Name: M2540 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasound pulsed doppler imaging system
Regulatory Class: II
Product Code: 90 IYN
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: December 20, 2001
Received: December 21, 2001

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 M2540 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

21221B (C1914C) Non-Imaging Pencil Transducer
21223B (D5014V) Non-Imaging Pencil Transducer
21228B (D1914V) Non-Imaging Pencil Transducer
21321A (C3540) Curved Linear Array Transducer
21330A (S4) Sector Transducer
21336A (E6509) Endocavity Transducer
21350A (S8) Sector Transducer
21359A (L7535) Linear Array Transducer
21360A (L5035) Linear Array Transducer
21369A (Omni II) TEE Sector Transducer
21373A (C5040) Curved Linear Array Transducer
21373B (C5040) Curved Linear Array Transducer
21376A (L1038) Linear Array Transducer
21380A (S12) Sector Transducer
21390A (15-61) Linear Array Transducer
21422A Sector Transducer
21425A Curved Linear Array Transducer
21446A Endocavity Transducer
21475A Linear Array Transducer

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 Robert A Phillips at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

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

Enclosure(s)

K014191

4.3.2 Indications for Use Tables

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) number: K 014191

Device name: Philips Medical Systems M2540 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	N		N	N	N	N	N
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (vascular/epicardial)	N	N	N	N	N	N	N
	Intra-operative (Neuro)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (thyroid, scrotum, breast)	N	N	N		N	N	N
	Neonatal Cephalic	N	N	N	N	N	N	N
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N	N	N	N	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	Other (Fetal)	N	N	N		N	N	N
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N
	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)	N	N	N		N	N	N

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging

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

NO previous 510(k) submissions 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014191

5/6/11

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21221B (C1914C) Non-Imaging Pencil transducer

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							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes include: None
Combined modes: None.
Previous submission: **K002470**, Adult & Pediatric cardiac

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21223B (D5014V) Non-Imaging Pencil transducer

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							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			N	N			
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: None
Combined modes: None
Previous submission: K002470, Peripheral vascular

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

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21228B (D1914V) Non-imaging pencil transducer

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							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N	N			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			N				
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: None
Combined modes: None
Previous submission: K002470 for Peripheral vascular

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21321A (C3540) Curved linear array transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (thyroid, scrotum, breast)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N		N	N	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging

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

Previous submission: **K002470** for fetal, abdominal and PV; **K990400** for fetal, pediatric, abdominal, small parts and PV

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

Prescription Use (Per 21 CFR 801.109)

Mary C. Brayton

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21330A (S4) Sector transducer

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	N		N	N	N	N	N
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N	N	N	N	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging

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

Previous submission: K002470 for Abdominal, Adult Cephalic, Cardiac, PV, Fetal and Ophthalmic; K990400 for Abdominal, Adult cephalic, Adult Cardiac; K990339 for Abdominal, Adult cephalic, Cardiac, Fetal and Ophthalmic; K980687 for Abdominal, Adult Cephalic, Fetal, Adult Cardiac, Ophthalmic and Harmonic Imaging

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21336A (E6509) Endocavity transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Prostate)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging

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

Previous submission: K990339 for Fetal, Endorectal, Endovaginal, Small Parts; K972348 Endovaginal, Endorectal, Gynecological, Obstetrics, Urological

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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 K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21350A (S8) Sector transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic	N	N	N		N	N	N
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Pelvic)	N	N	N	N	N	N	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging

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

Previous submission: K002470 for abdominal, adult & pediatric cardiac

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21359A (L7535) Linear array transducer

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							
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (thyroid, scrotum, breast)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging

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

Previous submission: K954028 for PV, Pediatrics, Abdominal, Small Parts, and Musculo-skeletal (conventional)

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Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21360A (L5035) Linear array transducer

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							
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (thyroid, scrotum, breast)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging

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

Previous submission: K954028 for Vascular, Pediatrics, Musculo-Skeletal (conventional) and Abdominal.

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21369A (Omni II) TEE Sector transducer

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							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N	N	N		N
	Cardiac Pediatric	N	N	N	N	N		N
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Doppler Tissue Imaging, Directional Angio

Combined modes: Duplex = 2D + Doppler

Previous submission: K954028 for Adult & pediatric cardiac, transesophageal

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21373A (C5040) Curved Linear array transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N		N	N	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N		N	N	N
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging

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

Previous submission: (K954028) for Fetal, Small Parts, Abdominal, Neonatal Cephalic, Cardiac and Vascular.

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

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21373B (C5040) Curved Linear array transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N		N	N	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N		N	N	N
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging

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

Previous submission: the 21373A was previously cleared (K954028) for Fetal, Small Parts, Abdominal, Neonatal Cephalic, Cardiac and Vascular.

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Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21376A (L1038) Linear transducer

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							
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Scrotum, Thyroid, Breast)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)	N	N	N		N	N	N

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging.

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

Previous submission: K990400 for Small parts, Peripheral Vascular and Musculo-skeletal (Conventional & Superficial).

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Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21380A (S12) Sector transducer

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							
	Abdominal							
	Intra-operative ((vascular/epicardial)	N	N	N	N	N	N	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic	N	N	N	N	N	N	N
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	
	Cardiac Pediatric	N	N	N	N	N	N	
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: K971116 for Intraoperative (cardiovascular), Pediatric, Cardiac (Adult & Pediatric), Peripheral Vascular

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21390A (15-6l) Linear array transducer

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							
	Abdominal							
	Intra-operative (vascular/epicardial)	N	N	N		N	N	N
	Intra-operative (Neuro)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N		N		N
	Small Organ (Thyroid)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)							

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

*Other modes: Amplitude Doppler, Panoramic, Directional Angio Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: K001711 for Intraoperative (cardiovascular & neurological), Small parts, Musculo-skeletal (conventional). K990330 for Intraoperative (Cardiovascular), Pediatric, Small Parts, Cardiac, Peripheral Vascular,

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(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21422A Sector transducer

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	N		N	N	N	N	N
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging

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

Previous submission: None.

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21425A Curved linear array transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N		N	N	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N		N	N	N
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: None.

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

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K014191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K_____

System: Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21446A Endocavity transducer

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N		N	N	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

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

*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: None.

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices
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