K034003

JAN - 8 2004

PHILIPS

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Philips Medical Systems

# 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: 26 November 2003

**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: HDI 5000 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 HDI 5000 system and transducers are substantially equivalent to the following currently marketed ultrasound system and transducers: HDI 5000, K961459, K991671, K002003; GE Voluson 730, K003525; Voluson 530, K940942; Antares, K023720.

**4) Device Description & Technical Comparison to Predicate Devices**

The HDI 5000 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 HDI 5000 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 HDI 5000 system and transducers are intended for diagnostic ultrasound imaging and fluid flow analysis of the human body.

**6) Conclusion**

The HDI 5000 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

JAN - 8 2004

Philips Ultrasound, Inc.
% Ms. Laura Danielson
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K034003
Trade Name: HDI 5000 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: December 23, 2003
Received: December 24, 2003

Dear Ms. Danielson:

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 HDI 5000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3D6-2 Trans- Abdominal Broadband Curved Array
C8-4v/8.0-4.0 MHz/11mm Curved Array

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: **HDI 5000 Ultrasound System**
Transducer:
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, Spine, Vascular)* | P | P | P | | P | 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 5,6,10,12, 13 |
| | Trans-vaginal | P | P | P | | P | Notes 1, 2, 3 | Notes 5, 6, 7,10,12, 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, 13 |
| | Cardiac Pediatric | P | P | P | P | P | Notes 1,2,3,4 | Notes 10, 11, 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:
*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 (Added to trans-vaginal in this submission.)
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES (Added to trans-vaginal in this submission.)

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

David A. Hoyn

Pres ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K034003

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **HDI 5000 Ultrasound System**
Transducer: **3D6-2 Trans- Abdominal Broadband Curved Array**
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 | N | N | N | | N | Notes 1, 3 | Notes 5, 6, 8, 10, 12, 13 |
| | Abdominal | N | N | N | | N | Notes 1,3 | Notes 5, 6, 8, 10, 12, 13 |
| | Intra-operative | | | | | | | |
| | 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 | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Fetal Echo | N | N | N | | N | 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
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*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
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Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

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

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K034003

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| Fetal Imaging & Other | Fetal | P | P | P | | P | Notes 1, 3 | Notes 5, 6, 10, 12 |
| | Abdominal | P | P | P | | P | Notes 1,2,3 | Notes 5, 6, 7, 10, 12 |
| | Intra-operative | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | P | P | P | | P | Notes 1, 2, 3 | Notes 5, 6, 7, 10, 12, **13** |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Conventional) | | | | | | | |
| | Musculo-skel. (Superficial) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (*Urology*) | P | P | P | | P | Notes 1, 3 | Notes 5, 10, 12 |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Fetal Echo | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Cerebral Vascular | | | | | | | |

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

David A. Feigal

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K034563