K133833
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510(k) Premarket Notification
Nuvis Diagnostic Ultrasound System

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

JAN 17 2014

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

Penny Greco
Philips Healthcare, Inc.
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810-6302
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Date prepared: December 10, 2012

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 and transducers

Proprietary Name: Nuvis Diagnostic Ultrasound System
Classification: Class II

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

3) Substantially Equivalent Devices

Philips Healthcare ClearVue Diagnostic Ultrasound System	K120321
Philips EPIQ C5-1 Transducer	K132304
Interson USB Ultrasound Probe System	K070907
Mobisante MobiUS	K102153

4) Device Description

The Nuvis Diagnostic Ultrasound systems is a mobile, general purpose, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation. Nuvis supports wireless network connectivity to allow the user to export (non-DICOM) ultrasound images.

The Nuvis system includes:

- A commercial off-the-shelf Android tablet (COTS)
- Nuvis software running as an app on the off-the-shelf tablet
- The C5-2 Curved linear array USB transducer

The Nuvis mobile system provides customers with a smaller, lower cost, and more easily leveraged ultrasound system.

5) Intended Use

> The Nuvis Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, and the Combined Mode (B+Color). The device is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Other-Urology, Other-Gynecology, and Other-Cardiac Fetal.
>
> The clinical environments where Nuvis can be used include hospital, clinic, and medical office settings for the diagnosis of patients.

6) Technological comparison to predicate devices

Philips ClearVue (K120321) and Nuvis are Track 3 systems that employ the same fundamental scientific technology. Nuvis leverages the common software platform used with other Philips ultrasound systems, including ClearVue.

The Nuvis C5-2 transducer is the same as the ClearVue C5-2 transducer, but with minor modifications including USB connectivity, which is similar to the Interson USB ultrasound transducers. The Nuvis C5-2 transducer has equivalent indications to the ClearVue C5-2 and EPIQ C5-1 transducers.

While the predicate, ClearVue, is a standard ultrasound system, Nuvis is a mobile system that runs on a commercial off the shelf tablet (COTS), similar to Interson USB and Mobisante MobiUS that run on commercially available devices.

Philips Nuvis is substantially equivalent to a the Mobisante MobiUS (K102153). Similar to the Mobisante MobiUS, the first release of Nuvis was tested for connection to a host computer. In the case of Nuvis the connection is to an Android tablet.

Similar to the Mobisante MobiUS (SP1), the Nuvis was verified with a commercial off-shelf computer/tablet. The Nuvis Android display is 7 inches, which is similar to, but larger than the Mobisante MobiUS SP1 display of 4.1 inches. Both the Mobisante system and Nuvis are battery operated, have WiFi technology and utilize USB connectivity for the ultrasound transducers. Both the MobiUS SP1 and Nuvis have up to 32 GB of internal storage. Nuvis has a display 1280 x 800 compared to the smaller MobiUS SP1 which is 800 x 480.

7) Determination of Substantial Equivalence

Non-clinical performance data

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- ISO 10993: Biological evaluation of medical devices.

Quality assurance measures applied to the system design and development include, but were not limited to:

- Rick Analysis
- Product Specifications
- Design Reviews
- Verification and Validation

Summary of Clinical Tests

The first release of Nuvis introduces no new indications for use, modes, features, or technologies relative to the predicate devices that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

8) Conclusions

Nuvis is substantially equivalent to the predicates identified above.

- Nuvis uses commercial off-the-shelf devices (COTS) similar to the predicates Interson USB and Mobisante MobiUS.
- Nuvis is indicated for the diagnostic ultrasonic imaging and fluid flow analysis similar to the predicates.
- Nuvis has the same gray-scale and Doppler capabilities as the predicates ClearVue and EPIQ.
- Nuvis uses essentially the same technologies for imaging, Doppler functions and signal processing as the predicates ClearVue and EPIQ.
- Nuvis has acoustic output levels below the Track 3 FDA limits the same as the predicates, ClearVue and EPIQ.
- Nuvis is manufactured under the same quality system as the predicates ClearVue and EPIQ.

- Both the predicate, ClearVue, and Nuvis are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Nuvis is designed and manufactured to the same electrical and physical safety standards as the predicates, ClearVue and EPIQ.

514 Performance Standards
There are no Sec. 514 performance standards for this device.

Prescription Status
This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Site(s)
Not applicable. No components supplied sterile.

Track
This is a Track 3 system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2014

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

Re: K133833
Trade/Device Name: Nuvis 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: November 11, 2013
Received: December 17, 2013

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson Sc2000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm 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 Small Manufacturers, International and Consumer Assistance 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,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Form Approved: OMB No. 0910-0120

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Expiration Date: December 31, 2013
See PRA Statement on last page.

Indications for Use

510(k) Number *(if known)*
K133833

Device Name

Philips Nuvis Diagnostic Ultrasound System

Indications for Use *(Describe)*

Philips Nuvis Diagnostic Ultrasound system is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, and Combined (B + Color) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Fetal/Obstetric
Abdominal
Other (Urology)
Other (Gynecology)
Other Cardiac (Fetal Echo)

The clinical environments where the Nuvis Diagnostic Ultrasound system can be used include hospital, clinical and medical office settings for the diagnosis of patients.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: Nuvis 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	PW D	CW D	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N				N	N	
	Abdominal	N				N	N	
	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 (Urology)	N				N	N	
	Other (Gynecology	N				N	N	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal Echo)	N				N	N	
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

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

Combined mode: B+Color
Previous submission:

(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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: C5-2

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	PW D	CW D	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N				N	N	
	Abdominal	N				N	N	
	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 (Urology)	N				N	N	
	Other (Gynecology)	N				N	N	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal Echo)	N				N	N	
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

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

Combined mode: B+Color
Previous submission:

(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)