K141369
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JUL 0 2 2014

Summary of Safety and Effectiveness

1) Submitter's name, address, telephone number, contact person:
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On Behalf of:
Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

This summary was prepared on 1st April, 2014.

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

Common/Usual Name: Diagnostic ultrasound system and transducers

Proprietary Name: VISIQ 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:

Device Name	510(k)
Philips Nuvis Diagnostic Ultrasound System	K133833
Philips ClearVue Diagnostic Ultrasound System	K120321

4) Device Description:
VISIQ is a new general imaging ultrasound system from Philips Ultrasound. VISIQ provides ultrasound capabilities in a portable, lightweight, affordable system. Its function is to acquire ultrasound data and to display the data in various modes of operation. VISIQ supports wireless network connectivity to allow the user to export ultrasound images.

The VISIQ system includes an off-the shelf tablet enclosed within a Philips Ultrasound enclosure. The system contains Philips software featuring a closed Operating System. The system can be used with the C5-2 Curved Linear Array USB Transducer.

5) Intended Use:

The VISIQ Ultrasound system is a general purpose, extremely portable, light weight ultrasound system that utilize Pioneer technology in USB probes, intended for use by customers in various clinical settings (private offices, clinics, small hospitals, large hospitals, primary and community healthcare centers) by different users (General Practitioners, Paraprofessionals, physician specialists including OBG's, Ultrasound Lab physicians, and nurse practitioners, etc., The System is intended for diagnostic ultrasound imaging in the following modes: 2D Auto Scan, M-mode, Pulse Wave Doppler, Color Doppler, Tissue Harmonics & iSCAN.

The system is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications, as listed in FDA's Diagnostic Ultrasound Indications for Use Form section 1.3 which includes Fetal/Obstetric, Abdominal, Small Organ (prostate) and Gynecological.

6) Technological comparison to predicate devices

Technological Characteristics

Feature	VISQ	ClearVue350/550 (K120321)	Nuvis (K133833)
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows
Indication for Use			
	Fetal/Obstetric	Fetal/Obstetric	Fetal/Obstetric
	Abdominal	Abdominal	Abdominal
	-	Pediatric	-
	Small Organ (prostate)	Small Organ (prostate)	-
	-	Neonatal Cephalic	-
	-	Adult Cephalic	-
	-	Trans-rectal	-
	-	Trans-vaginal	-
	-	Musculo-skel (conventional)	-
	-	Musculo-skel (superficial)	-
	Other	Other (Gynecological)	Other (Gynecological)

	(Gynecological)		
	-	Cardiac Adult	-
	-	Cardiac Pediatric	-
	-	Trans-esoph. (Cardiac)	-
	Other (Fetal)	Other (Fetal)	Other (Fetal)
	-	Peripheral vessel	-
	-	Other (Carotid)	-
	-	-	Other(Urology)
Transducer Types	The C5-2 Curved linear array USB transducer	S4-1 Sector Array C5-2 Curved Array C9-4v Curved Array L12-4 Broadband Sector Linear Array	The C5-2 Curved linear array USB transducer
Transducer Frequency	1-6Mhz	1-12Mhz	1-6Mhz
Modes of Operation	2D Auto Scan, M-mode, Pulse Wave Doppler, Color Doppler, Tissue Harmonics & iSCAN.	B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Harmonics, iSCAN, X-Res, angio, 3D (freehand), and SonoCT.	B (or 2-D(, Color Doppler, and the Combined Mode (B+Color)
PW Doppler	Available	Available	Available
CW Doppler	Available	Available	Available
Patient contact materials	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible
510(k) Track	Track 3	Track 3	Track 3
Regulatory Class	Class II	Class II	Class II

7) Determination of Substantial Equivalence

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

- IEC60601-1: Medical electrical equipment. General requirements for basic safety and essential performance
- IEC60601-1-2: Medical electrical equipment – Part 1-2: General requirements for Safety – Collateral standard: Electromagnetic Compatibility Requirements and Tests

- IEC60601-2-37: Medical electrical equipment. Particular requirements for the safety of ultrasound medical diagnostic and monitoring equipment.
- ISO 10993: Biological evaluation of medical devices.

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

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

Summary of Clinical Tests:
The first release of VISIQ 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

VISIQ is substantially equivalent to the predicates identified above.

- VISIQ and Nuvis use commercial off the shelf devices (COTS)
- Both the predicates, ClearVue and Nuvis have the same gray-scale and Doppler capabilities as VISIQ.
- Both the predicates, ClearVue and Nuvis use essentially the same technologies for imaging, Doppler functions and signal processing as VISIQ.
- Both the predicates, ClearVue and Nuvis have acoustic output levels below the track 3 FDA limits, which is the same for VISIQ.
- Both the predicates, ClearVue and Nuvis are manufactured of materials with equivalent biosafety as VISIQ. The materials have been evaluated and found to be safe for this application.
- Both the predicates, ClearVue and Nuvis are designed and manufactured to the same electrical and physical safety standards as VISIQ.

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
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

July 2, 2014

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

Re: K141369
Trade/Device Name: VISIQ 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: June 10, 2014
Received: June 11, 2014

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 VISIQ 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Michael D. O'Hara

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)*

K141369

Device Name

VISIQ Diagnostic Ultrasound System

Indications for Use *(Describe)*

Philips VISIQ Diagnostic Ultrasound system is intended for diagnostic ultrasound imaging in 2D Auto Scan, M-mode, Pulse Wave Doppler, Color Doppler, Tissue Harmonics & iSCAN.

The system is indicated for diagnostic ultrasound imaging and fluid flow analysis and supports the following Indications for Use: Abdominal, Cardiac other (Fetal), Fetal/Obstetric, Gynecological, and Small Organ (Prostate).

The clinical environments where the VISIQ Diagnostic Ultrasound system can be used include large/small hospitals, clinical and medical office settings, and primary and community healthcare centers 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)*

Michael D. O'Hara

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: VISIQ 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) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N(1-4)
	Abdominal	N	N	N		N	N	N(1-4)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (prostate)	N	N	N		N	N	N(1-4)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N		N	N	N(1-4)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N		N	N	N(1-4)
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

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

***Other modes:** 1. Tissue Harmonics, 2. iSCAN, 3. AutoScan, 4. X-Res
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD,
Previous submission: none

(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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: C5-2 transducer used with VISIQ 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) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N(1-4)
	Abdominal	N	N	N		N	N	N(1-4)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (prostate,)	N	N	N		N	N	N(1-4)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N		N	N	N(1-4)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)	N	N	N		N	N	N(1-4)
Peripheral Vessel	Peripheral vessel							
	Other (specify)							

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

***Other modes:** 1. Tissue Harmonics, 2. iSCAN, 3. AutoScan, 4. X-Res
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD
Previous submission: none

(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)