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

November 16, 2016

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

Re: K163020
Trade/Device Name: Xperius Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 28, 2016
Received: October 31, 2016

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.

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" (21 CFR 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163020

Device Name
Xperius Ultrasound System

Indications for Use *(Describe)*

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

Peripheral Vessel

The clinical environments where the Xperius Ultrasound system can be used for are: hospitals, surgery centers, clinics, and physician offices.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: TBD
Device name: Xperius 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	PW D	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
`	Fetal /Obstetric							
	Abdominal	N				N		N(3,4,6,8,9)
	Intra-operative (Vascular)							
	Intra-operative (Neuro)							
Fetal Imaging & Other	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N				N		N(3,4,6,8,9)
	Cerebral Vascular							

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

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging 6. SonoCT 7. Biopsy Guidance 8. Needle Visualization Regional anesthesia, Nerve 9., Vascular access
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	

(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)

510(k) Number: TBD
System: Xperius Ultrasound system
Device name: L12-4
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	PW D	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
` Fetal Imaging & Other	Fetal /Obstetric							
	Abdominal	P				P		P(3,6) N(4,8 ,9)
	Intra-operative (Vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N				N		P(3,6) N(4, 8 ,9)
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K162329; E= added under Appendix E

Other Modes	
1. Harmonic (Tissue or Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. SonoCT
3. iScan	7. Biopsy Guidance
4. X-Res	8. Needle Visualization, Regional Anesthesia, Nerve
	9. Vascular Access
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	

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

Prescription Use (Per 21 CFR 801.109)

510(k) No: _____TBD_____
System: Xperius Ultrasound System
Transducer: C5-2
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	PW D	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
` Fetal Imaging & Other	Fetal /Obstetric							
	Abdominal	P				P		P(3,4,6) N 8
	Intra-operative (Vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P				P		P(3,4,6) N 8
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA **K153480**

Other Modes	5. Angio Imaging
1. Harmonic (Tissue or Contrast)	6. SonoCT
2. Tissue Doppler Imaging	7. Biopsy Guidance
3. iScan	8. Regional Anesthesia, Nerve
4. X-Res	9. Vascular Access

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)

510(k) Summary of Safety and Effectiveness

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

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

Saraswathi Deora
Program Manager- Q&R-Regulatory Affairs
Saraswathi.Deora@philips.com
On Behalf of:
Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

Date prepared: Sep 27, 2016

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: Xperius 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

Primary Predicate Device

Philips CX50 and Sparq Diagnostic Ultrasound System	K162329	09/14/2016
Philips ClearVue 850 Diagnostic Ultrasound System	K153480	12/16/2015

Reference Device

SonoSite NanoMaxx Series Ultrasound System	K101757	08/12/2012
eZono **3000**	K120234	04/19/2012

4) Device Description

The proposed Xperius Ultrasound System is a general purpose, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation.

The Xperius Ultrasound System is substantially equivalent to the currently marketed and predicate Philips CX50 and Sparq Diagnostic Ultrasound System K162329 and ClearVue 850 K153480 in terms of design and fundamental scientific technology. The Xperius Ultrasound System is provided with additional indications.

5) Intended Use

Philips Xperius Ultrasound system is intended for diagnostic Ultrasound imaging in B (2D) and Color Doppler modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:
Abdominal
Peripheral Vessel

The clinical environments where the Xperius Ultrasound system can be used for are: hospitals, surgery centers, clinics, and physician offices.

6) Comparison of the Design and Technological characteristics
A comparison of the design and technological characteristics of the proposed Xperius System to the currently marketed and predicate Sparq and ClearVue850 is provided in Table 1 below:

Technological Characteristics

Feature	Proposed Xperius Ultrasound System	Predicate CX 50 Sparq System (K162329)	Predicate ClearVue850 K153480
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	

Indication for Use			
	-	Ophthalmic	
	-	Fetal/Obstetric	Fetal/Obstetric
	Abdominal	Abdominal	Abdominal
		Intraoperative (vascular/epicardial)	-
		-	-
	-	Small Organ (thyroid, scrotum, breast)	Small Organ (breast, thyroid, testicle)
	-	Adult Cephalic	Adult Cephalic
	-	Trans-rectal	Trans-rectal
	-	Trans-vaginal	Trans-vaginal
	-	Musculo-skel (conventional)	Musculo-skel (conventional)
	-	Musculo-skel (superficial)	Musculo-skel (superficial)
	-	Other (Gynecological)	Other (Gynecological)
	-	Cardiac Adult	Cardiac Adult
	-	Trans-esoph. (Cardiac)	Trans-esoph. (Cardiac)
	Peripheral vessel	Peripheral vessel	Peripheral vessel
	-	-	Pediatric Neonatal Cephalic Cardiac Pediatric Other (Fetal) Other (Carotid) Cerebral Vascular Other: Urology

Transducer Types	**C5-2 Curved Array** **L12-4 Broadband Sector Linear Array**	C5-1 L15-7io X7-2t C6-2 C9-4v **L12-4** S4-2	S4-1 Sector Array **C5-2 Curved Array** C9-4v Curved Array L12-4 Broadband Sector Linear Array 3D9-3V V6-2 L12-5 D2CWc
Transducer Frequency	**1-6Mhz**	1-12Mhz	1-12Mhz
Modes of Operation	B (or 2-D) Color Doppler, **modes includes Regional Anesthesia, Vascular access, Needle Visualization X-res, SonoCT, iSCAN**	B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. **Needle Visualization** i**Scan** **4. X-Res, Sono CT**	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), 4D and SonoCT, Combined modes includes FloVue, Elastography (strain).
PW Doppler	Not Available	Available	Available
CW Doppler	Not 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

Xperius Ultrasound System is a Track 3 system that employs the same fundamental scientific technology as that cleared with currently marketed and predicate Philips CX50 and Sparq Diagnostic Ultrasound System (K162329) and ClearVue850 K153480. The primary difference with an additional indication for use.

Xperius Ultrasound System is designed to cater to the specific target market in Ultrasound Guided Regional Anesthesia and Vascular Access by leveraging the Philips Common platform architecture and design which is used for developing the predicate devices such as CX50, Sparq and ClearVue products.

6) Determination of Substantial Equivalence

Non-clinical performance data

Non-clinical tests performed on in this premarket notification submission for a determination of substantial equivalence demonstrates 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

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

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

Summary of Clinical Tests

The Xperius Ultrasound System introduces no new indications for use, modes, features, or technologies as compared to the currently marketed and predicate devices Philips CX50 and Sparq Diagnostic Ultrasound System (K162329) and ClearVue850 (K153480) the reference systems K101757 that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both the currently marketed predicate and subject devices.

7) Conclusions

Proposed Xperius Ultrasound system is substantially equivalent to the currently marketed and predicates in terms of indications for use, design, indications for use and technological characteristics.

Xperius Ultrasound system is same as Philips CX50 and Sparq Diagnostic Ultrasound System (K162329) and ClearVue850 (K153480) transducers L12-4 and C5-2 and additional indications.

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