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

October 23, 2018

Re: K182529
Trade/Device Name: Xperius Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 15, 2018
Received: October 16, 2018

Dear Mark 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13002 26759, cn=Michael D. O'hara -S
Date: 2018.10.23 17:30:49 -04'00'

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182529

Device Name
Xperius Ultrasound System

Indications for Use *(Describe)*
Philips Xperius Ultrasound system is intended for diagnostic Ultrasound imaging in B (2D), Color Doppler, M-Mode, and Color Power Angio (CPA) modes. It is indicated for diagnostic ultrasound imaging, and fluid flow analysis in the following applications:
Abdominal
Peripheral Vessel
MSK
Small Organ
Pediatric

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)

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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 Imaging & Other	Fetal /Obstetric							
	Abdominal	P	N			P		P(3,4,6,8,9) N(5)
	Intra-operative (Vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N			N		N(5)
	Small Organ (breast, thyroid, testicle)	N	N			N		N(5)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N			N		N(5)
	Musculo-skel. (Superficial)	N	N			N		N(5)
	Intra-luminal							
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	N			P		P(3,4,6,8,9) N(5)
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K163020; E= added under Appendix E

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging (CPA) 6. SonoCT 7. Biopsy Guidance 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) 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	N			P		P(3,4,6,8,9) N(5)
	Intra-operative (Vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N			N		N(5)
	Small Organ (breast, thyroid, testicle)	N	N			N		N(5)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N			N		N(5)
	Musculo-skel. (Superficial)	N	N			N		N(5)
	Intra-luminal							
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	N			P		P(3,6,4 8,9) N(5)
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA K163020; E= added under Appendix E

Other Modes	
1. Harmonic (Tissue or Contrast) 2. Tissue Doppler Imaging 3. iScan 4. X-Res	5. Angio Imaging (CPA) 6. SonoCT 7. Biopsy Guidance 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	N			P		P (3,4,6,8) N(5)
	Intra-operative (Vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N			N		N(5)
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N			N		N(5)
	Musculo-skel. (Superficial)	N	N			N		N(5)
	Intra-luminal							
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P				P		P (3,4,6,8) N(5)
	Cerebral Vascular							

N= new indication; P= previously cleared by FDA **163020;** E= added under Appendix E

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

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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) 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: October 19, 2018

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 Xperius Ultrasound System	K163020	11/16/2016
Reference Devices		
Philips ClearVue 850 Diagnostic Ultrasound System	K153480	12/16/2015
Philips CX50 and Sparq Diagnostic Ultrasound Systems	K162329	09/14/2016
Philips Lumify Ultrasound System	K162549	10/05/2016

4) Device Description

The modified/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 modified Xperius Ultrasound System is substantially equivalent to the currently marketed and predicate Philips Xperius Ultrasound System (K163020), Philips ClearVue 850 Diagnostic Ultrasound System (K153480) in terms of design and fundamental scientific technology. The modified Xperius Ultrasound System is provided with additional indications.

5) Intended Use

Philips Xperius Ultrasound system is intended for diagnostic Ultrasound imaging in B (2D), Color Doppler, M- Mode, and Color Power Angio (CPA) modes. It is indicated for diagnostic ultrasound imaging, and fluid flow analysis in the following applications:
Abdominal
Peripheral Vessel
MSK
Small Organ
Pediatric

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 Xperius is provided in Table 1 below:

Technological Characteristics

Feature	Proposed Xperius System	Predicate Xperius System (K163020)	Reference 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	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows
Indication for Use	-	-	Fetal/Obstetric
	Abdominal	Abdominal	Abdominal
	Small Organ (thyroid, scrotum, prostate, breast)	-	Small Organ (breast, thyroid, testicle)
	-	-	Adult Cephalic
	-	-	Trans-rectal
	-	-	Trans-vaginal
	Musculo-skel (conventional)	-	Musculo-skel (conventional)
	Musculo-skel (superficial)	-	Musculo-skel (superficial)
	-	-	Other (Gynecological)
	-	-	Cardiac Adult
	-	-	Trans-esoph. (Cardiac)
	Peripheral vessel	Peripheral vessel	Peripheral vessel
	Pediatric	-	Pediatric Neonatal Cephalic Cardiac Pediatric Other (Fetal) Other (Carotid)

Feature	Proposed Xperius System	Predicate Xperius System (K163020)	Reference ClearVue850 (K153480)
			Cerebral Vascular
Transducer Types	**C5-2 Curved Array** **L12-4 Broadband Sector Linear Array**	**C5-2 Curved Array** **L12-4 Broadband Sector Linear Array**	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	**1-6 Mhz**	**1-6Mhz**	1-12Mhz
Modes of Operation	B (or 2-D) Color Doppler, M-mode and Color Power Angio (CPA) modes modes **include Regional Anesthesia, Vascular access, Needle Visualization, X-Res, SonoCT, iSCAN)**	B (or 2-D) Color Doppler, **modes include 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 Harmonics, iSCAN, X-Res, Color Power Angio, 3D (freehand), 4D and SonoCT, Combined modes includes FloVue, Elastography (strain).
PW Doppler	-	Not Available	Available
CW Doppler	-	Not Available	Available
Patient contact materials	-	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible	Acrylonitrile butadiene styrene Silicone Rubber PVC - Flexible
510(k) Track	-	Track 3	Track 3

Feature	Proposed Xperius System	Predicate Xperius System (K163020)	Reference ClearVue850 (K153480)
Regulatory Class	-	Class II	Class II

Modified and proposed Xperius System is a Track 3 system that employs the same fundamental scientific technology as that cleared with currently marketed and predicate Philips Xperius Ultrasound System (K163020). The primary difference with an additional indication for use and additional Modes of Operation.

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
Software Revision	1.5	1	N/A	N/A	N/A
Analysis	Same	Non-Qlab quantification is explored, basic measurements, calculations, their configuration and use. Depth and distance measurement	Same	Same	Same
Annotation	Same	Users describe the imaging situation and findings, both during the imaging session and in review, by adding words, phrases and body marker graphics to the images.	Same	Same	Same
Capture	Same	Single frame and multi frame images (loops) are saved in a persistent manner for later review. The workflow and techniques surrounding prospective and retrospective capture of these images is considered, along with the system impact of offering different post- processing capabilities on the saved data, as well as the size and timing constraints of the platform.	Same	Same	Same
Cineloop	Same	Immediate review of a frozen imaging data set is called Cineloop (also known as Quick Review). The feature covers the behavior of all of the imaging modalities.	Same	Same	Same

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
Color	In addition to Color Flow , CPA was added Color Power Angio (CPA): Real time two-dimensional imaging composed of a gray scale image with flow amplitude displayed as a color overlay.	The feature covers Color Flow.	The feature covers Color Flow, CPA, TDI (Tissue Doppler Imaging) and BFlow.	2D Color Doppler Imaging Tissue Doppler Imaging and Harmonics (Tissue and Contrast) Combination modes	The feature covers Color Flow
Connectivity	Same	DICOM protocol support for networks, printers, servers, and removable media.	Same	Same	Same
DNL	Same	The Digital Navigation Link (DNL) provides a peer-topeer network connection to an external interventional workstation transmitting 2D and 3D ultrasound image data in real-time. Communication between the two systems is handled over a DICOM-like communication protocol.	Same	Same	Same
Echo	Same	2D black and white image generation, acquired black and white Mmode data, and anatomical Mmode are covered by this feature.	Same	Same	Same
External AV Support	Same	Ultrasound systems support connections to external audio/visual devices, such as external monitors (for operating room or additional viewing during scans, and for trade-show exhibits with large screen monitors), external	Same	N/A	N/A

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
		real-time capture devices (e.g. VCR and DVR), and external single frame capture devices (e.g. printers). We may also have support of an integrated (i.e. controlled by the system) VCR or DVR with the system – both the recording of voice and video onto the device and replay of the device back into the system.			
Help	Same	The display of helpful information to the user during the use of the ultrasound system.	Same	Same	Same
iSPI	Same	The intelligent Service Platform Interface that provides common service features across Philips products.	Same	N/A	N/A
Install and Upgrades	Same	Installation of software and hardware capabilities by all affected users of the system: field service, manufacturing, engineers, and end users (for upgrades and patches).	Same	Same	Same
Localization	No new languages. Additional user manuals: Czech, Slovak and Korea	Provides the user with the ability to use the system with their localization settings. This includes the user interface language, the keyboard language, and the locale for numeric, and time display settings.	Same	Same	Same
Output Control System	Same	The Output Control System (OCS) monitors and controls acoustic and thermal output emitted from the system through the transducer. Its design must meet system requirements imposed by regulating industries. OCS exposes the Auto-Test Interface (ATI) used by the	Same	Same	Same

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
		Acoustic Measurement Department (AMD) to collect system data and verify OCS operation.			
Peripherals	Same	Peripherals assigns external devices, such as printers and VCRs, to system hard keys and foot switches, and manages tertiary devices such as ambient light sensor and barcode scanner. Peripheral : Printer	Same	Same	Same
Power Management	Touch power switch at the front of the tablet, Lock button for locking the screen, Increased battery run time, User replaceable battery	System startup and shutdown is more complex with the portable nature of the system. Treating power management as a feature allows us to look at all the user interactions surrounding turning on and off the system with and without wall power (battery operations), portable mode, low and	Same	Same	Same
Presets	New: FAST and Lung presets and M-Mode and CPA Mode added in Xperius 1.5 Color Power Angio (CPA): Real time two-dimensional imaging composed of a gray scale image with flow amplitude displayed as a color overlay. M-Mode (MM): Gray scale time motion display having a	Presets manages persistent collections of system settings. Preset collections are stored, loaded, activated, backed-up, exported, and imported. Activation of a preset collection enhances clinical workflow by configuring the system for a specific use. Factory presets can be fine- tuned by the user's creating a custom preset. The menu that offers presets for activation can also be tailored by the user. Tissue specific Presets" Nerve 0-4. Nerve 4-6 and vascular access	Same ClearVue 850 supports Modes of Operation: B (or 2-D), M-mode (including Anatomical M- mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Harmonics, iSCAN, X-Res, Color Power Angio, 3D (freehand), 4D and SonoCT, Combined modes	CX50 Supports FAST and Lung Presets	Lumify Supports FAST and Lung Presets

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
	selectable scroll rate. In some screen formats includes a 2D mode image. IQ (Image Quality) Optimization of the previously cleared presets - Nerve 0-4 , Nerve 4-6 and Vascular Access to enhance nerve and vessel visualization		includes FloVue, Elastography (strain).		
Reporting	Same	Creation of a patient report from the data entered into and acquired with the ultrasound system.	Same	Same	Same
Review	Same	Review of stored images, measurements and patient information has unique workflow. Display and replay of the images, along with post-processing capabilities is explored for the platform. Includes ability to de-identify image and exam information on both the display and in exported images.	Same	Same	Same
Security	Same	A collection of system capabilities that allow the ultrasound device to integrate with customer sites protecting the device and customer infrastructure from malware and	Same	Same	Same

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
		protecting patient data from unauthorized access. Features include: Auditing, Encryption, Whitelisting, and network time service.			
Service	Same	System capabilities for the user of field service personnel to install, diagnose and repair an ultrasound system. Special workflow is considered as well as special tools or software not used by the end clinical user. Local and Remote service workflows and tools are discussed Remote Self Test is also included in this feature as a special topic.	Same	Same	Same
Study Management	Same	Overall creation, addition to and deletion of a patient's information, images, quantification findings and reports.	Same	Same	Same
Transducers	Same C5-2 and L12-4No new or additional transducers are added to Xperius Ultrasound System 1.5 revision	Transducers detects the presence of a transducer in a connector, recognizesthe transducer model, manages the system files and stored parameters associated with the transducer, and selects the active transducer among those connected. Transducers implements the special functions for TEE, bi-plane, matrix, and mechanical 3D transducers. C5-2, L12-4	ClearVue850 supports S4-1 C5-2 , C9-4v ,L12-4 ,3D9-3V,V6-2, L12-5 D2CWc	CX50 Supports C5-1 C8-5 C9-3io C9-3v C10-3v D2cwc D5cwc L10-4 lap L12-3 L12-5 50 L15-7io S5-1 S8-3 S12-4 S7-3t	Lumify supports C5-2, L12-4,

Features	Proposed Xperius Ultrasound System	Predicate Xperius Ultrasound System (K163020)	Reference ClearVue 850 Ultrasound System (K153480)	Reference CX50 Ultrasound System (K162329)	Reference Lumify Ultrasound System (K162549)
User Management	Same	User Management authenticates, identifies, and grants rights and privileges to users. It supports identifying, auditing, and tracking system usage and customization and configuration of the system. The presence or absence of an authenticated user also	Same	Same	Same
SonoCT	Same	Acquires multiple lines of sight and compounds them in real time. The images have fewer artifacts, improved contrast resolution and better defined tissue margins.	Same	Same	N/A
XRes	Same	Adaptive image processing enhances image quality through millions of calculations. XRES works in tandem with SonoCT to further reduce artifacts, and improve contrast resolution and border definition.	Same	Same	N/A

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

- AAMI/ANSI ES 60601-1:2005/(R)2012 And A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance). IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance
- AAMI/ANSI/IEC 60601-1-2: 2014: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests and IEC 60601-1-2:2014: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- ISO 10993: Biological evaluation of medical devices
- 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 proposed Xperius Ultrasound System did not require clinical studies since substantial equivalence to the currently marketed predicate devices, Philips Xperius Ultrasound System was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

7) Conclusions

Proposed Xperius 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 Xperius Ultrasound System (K163020) with additional indications and modes of operation.

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.