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

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

October 5, 2016

Re: K162549
Trade/Device Name: Lumify Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 10, 2016
Received: September 13, 2016

Dear Mr. Job:

This letter corrects our substantially equivalent letter of 10/3/2016.

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)*
K162549

Device Name
Lumify Ultrasound System

Indications for Use *(Describe)*
Philips Lumify Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B + Color), and M modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:
Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac.

Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

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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FOR FDA USE ONLY

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: _____

Device name: Lumify 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	**P**	**N**			**P**	**P**	
	Abdominal	**P**	**N**			**P**	**P**	
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**N**	**N**			**N**	**N**	
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**N**			**P**	**P**	
	Neonatal Cephalic	**N**	**N**			**N**	**N**	
	Adult Cephalic	**N**	**N**			**N**	**N**	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**N**			**P**	**P**	
	Musculo-skel (superficial)	**P**	**N**			**P**	**P**	
	Other (Urology)	**P**	**N**			**P**	**P**	
	Other (Gynecology	**P**	**N**			**P**	**P**	
Cardiac	Cardiac Adult	**N**	**N**					
	Cardiac Pediatric	**N**	**N**					
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal Echo)	**P**	**N**			**P**	**P**	
Peripheral Vessel	Peripheral vessel	**P**	**N**			**P**	**P**	
	Other (Carotid)	**P**	**N**			**P**	**P**	

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

Combined mode: B+Color
Previous submission: K152899, K153480

(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	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	**P**	**P**			**P**	**P**	
	Abdominal	**P**	**P**			**P**	**P**	
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**			**P**	**P**	
	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)	**P**	**P**			**P**	**P**	
	Other (Gynecology)	**P**	**P**			**P**	**P**	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal Echo)	**P**	**P**			**P**	**P**	
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: K152899, K153480

(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: L12-4

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							
	Abdominal	**P**	**P**			**P**	**P**	
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**			**P**	**P**	
	Small Organ (thyroid, scrotum, prostate, breast)	**P**	**P**			**P**	**P**	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	**P**	**P**			**P**	**P**	
	Musculo-skel (superficial)	**P**	**P**			**P**	**P**	
	Other (Urology)							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	**P**	**P**			**P**	**P**	
	Other (Carotid)	**P**	**P**			**P**	**P**	

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

Combined mode: B+Color
Previous submission: K152899, K153480

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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: S4-1

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	**P**	**P**			**P**	**P**	
	Abdominal	**P**	**P**			**P**	**P**	
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	**P**	**P**			**P**	**P**	
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	**P**	**P**			**P**	**P**	
	Adult Cephalic	**P**	**P**			**P**	**P**	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Urology)							
	Other (Gynecology)	**P**	**P**			**P**	**P**	
Cardiac	Cardiac Adult	**P**	**P**			**P**	**P**	
	Cardiac Pediatric	**P**	**P**			**P**	**P**	
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal Echo)							
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: (predicate K153480)

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

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

Penny Greco
Philips Healthcare, Inc.
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810-6302
Tel: (978) 659-4615
Fax (978) 975-7324

Date prepared: September 7, 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: Lumify 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

Lumify Ultrasound System	K152899	10/30/2015

Reference Device

ClearVue Ultrasound System	K153480	12/16/2015

4) Device Description

The Lumify Ultrasound System with the S4-1 transducer and new intended use environments 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. Lumify supports wireless network connectivity to allow the user to export ultrasound images.

The Lumify Ultrasound System includes:

- A commercial off-the-shelf Android device (COTS)
- Philips ultrasound software running as an app on the off-the-shelf device
- The C5-2 Curved array USB transducer
- The L12-4 Linear array USB transducer
- The S4-1 Sector array USB transducer

The Lumify Ultrasound System provides customers with a smaller, lower cost, and more easily leveraged ultrasound system.

5) Intended Use

The Lumify Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, the Combined Mode (B+Color) and M-Mode. The device is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, and Cardiac.

The Lumify Ultrasound System is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

5) Technological comparison to predicate devices

The Lumify Ultrasound System is a Track 3 system that employs the same fundamental scientific technology as that cleared with K152899. The primary difference between Lumify submitted in K152899 is the addition of the S4-1 (K153480) transducer for the cardiac indication, the additional M mode, pediatric indication, and the new use environments: home and transport for use by healthcare professionals. The additional Lumify indications for use and mode of operation were cleared with the Philips ClearVue S4-1 (K153480).

6) 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 tests which show 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
- IEC 60601-1-11:2015: Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 60601-1-12:2015: Medical Electrical Equipment - Part 1-12: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

Quality assurance measures 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 Lumify Ultrasound System introduces no new indications for use, modes, features, or technologies relative to the predicate devices (Lumify/ClearVue) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

7) Conclusions

The Lumify Ultrasound System is substantially equivalent to the predicates identified above.

The Lumify Ultrasound System is essentially the same as the Lumify Ultrasound System (K152899) but with the S4-1 transducer (K153480), additional indications, mode of operation, and new intended use environments.

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