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

Sonoscanner
% E. J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

August 3, 2017

Re: K171164
Trade/Device Name: U-Lite EXP
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 31, 2017
Received: August 1, 2017

Dear E. J. Smith:

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,

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 on last page.

510(k) Number *(if known)*

K171164

Device Name
U-Lite EXP

Indications for Use *(Describe)*

U-Lite is indicated for the visualization of structures and dynamic processes in the human body using ultrasound imaging and fluid flow analysis for diagnosis in the following clinical applications:

Abdominal
Small Parts
Vascular
Cardiac
Obstetrics
Gynecology
Fetal
Pediatrics

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)

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 Format

Probe: PR50: Convex probe for U-Lite EXP

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	**Mode of Operation**								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (B+Color Doppler)**	**Other** (Specify)**
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N		N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N		N		N	N	N	N	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card)									
Musculo-skeletal (Conventional)	N		N		N	N		N	
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Gynecological)	N				N	N	N	N	
Peripheral Vessel									
Urology (including prostate)	N				N	N	N	N	

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

Diagnostic Ultrasound Indications for Use Format

Probe: PR51: Linear probe 40mm for U-Lite EXP

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	**Mode of Operation**								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (B+Color Doppler)**	**Other** (Specify)**
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)	N		N		N	N	N	N	
Neonatal Cephalic	N		N		N	N	N	N	
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card)									
Musculo-skeletal (Conventional)	N		N		N	N	N	N	
Musculo-skeletal (Superficial)	N		N		N	N	N	N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral Vessel	N		N		N	N	N	N	
Urology (including prostate)									

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

Diagnostic Ultrasound Indications for Use Format

Probe: PR52: Linear probe 50mm for U-Lite EXP

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	**Mode of Operation**								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (B+Color Doppler)**	**Other** (Specify)**
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)	N		N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card)									
Musculo-skeletal (Conventional)	N		N		N	N	N	N	
Musculo-skeletal (Superficial)	N		N		N	N	N	N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral Vessel	N		N		N	N	N	N	
Urology (including prostate)									

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

Diagnostic Ultrasound Indications for Use Format

Probe: PR53: Endocavitary probe for U-Lite EXP

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	N		N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Gynecological)	N		N		N	N	N	N	
Peripheral Vessel									
Urology (including prostate)	N		N		N	N	N	N	

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

Diagnostic Ultrasound Indications for Use Format

Probe: PR54: Phased Array probe for U-Lite EXP

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (B+Color Doppler)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N		N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N		N		N	N	N	N	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card)									
Musculo-skeletal (Conventional)	N		N		N	N	N	N	
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult	N	N	N		N		N	N	
Cardiac Pediatric	N	N	N		N		N	N	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Gynecological)	N				N	N	N	N	
Peripheral Vessel									
Urology (including prostate)	N				N	N	N	N	

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

Diagnostic Ultrasound Indications for Use Format

Probe: PR55: MicroConvex probe for U-Lite EXP

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (B+Color Doppler)	Other** (Specify)
Ophthalmic									
Fetal	N		N		N	N	N	N	
Abdominal	N		N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N		N		N	N	N	N	
Small Organ (breast, testes, thyroid)	N		N		N	N	N	N	
Neonatal Cephalic	N		N		N	N	N	N	
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card)									
Musculo-skeletal (Conventional)	N		N		N	N	N	N	
Musculo-skeletal (Superficial)	N		N		N	N	N	N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral Vessel	N		N		N	N	N	N	
Urology (including prostate)	N		N		N	N	N	N	

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

510(k) Summary

Sponsor:	Sonoscanner
Address:	6 rue Andre Voguet Ivry Sur Seine, France 94200
Telephone Number:	+33 954-971-557
Email Address:	richard@sonoscanner.com
Contact Person:	Bruno Richard Scientific Director, Quality Manager

Summary Preparation Date:	July 31, 2017

DEVICE NAME:

Trade Name:	U-Lite EXP
Common/Usual Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Name:	Ultrasonic Pulsed Doppler Imaging System
Regulation Number:	21 CFR 892.1550, 21 CFR 892.1560 and 21 CFR 892.1570
Product Code:	IYN, IYO and ITX
Device Class:	Class II
Panel:	Radiology

DEVICE DESCRIPTION:

The U-Lite EXP are notebook-size, battery operated, general purpose track 3 diagnostic ultrasound system. It is used to acquire and display high-resolution, real-time ultrasound data and display the data as B Mode, Color Mode, Power Doppler Imaging, and Pulse Wave Doppler spectrum.

The handheld U-Lite EXP tablet's display is a high-resolution 7-inch color LED screen and the controls are intuitive and easy to use. Controls are touch-activated – there are no knobs or switches. The U-Lite EXP is equipped with a lithium-ion battery. When fully charged, the battery can give the system a total autonomy of up to 1h30 in the scanning mode.

INDICATIONS FOR USE:

U-Lite is indicated for the visualization of structures and dynamic processes in the human body using ultrasound imaging and fluid flow analysis for diagnosis in the following clinical applications:

Abdominal

Small Parts

Vascular

Cardiac

Obstetrics

Gynecology

Fetal

Pediatrics

PREDICATE PRODUCT COMPARISON:

Predicate Product Comparison Table

DEVICE COMPARISON TABLE			
Parameters	U-Lite K143601	U-Lite EXP	Comment
Intended Use	Intended for diagnostic ultrasound analysis and fluid flow analysis	Intended for diagnostic ultrasound analysis and fluid flow analysis	Identical
Track	Track 3	Track 3	Identical
Dimensions	7.5 x 5.3 x 0.8 inches	7.5 x 5.3 x 0.8 inches	Identical
Weight	1.8 lbs	1.8 lbs	Identical
Configuration/Design	Notebook, handheld	Notebook, handheld	Identical
Battery Life	1hr 30mins	1hr 30mins	Identical
Display Size	7in	7in	Identical
Table Top Docking	Yes	Yes	Identical
Mobile Cart	No	Yes	Added

Scanning Modes			
B Mode	Y	Y	Identical
Color Mode	Y	Y	Identical
Power Doppler	Y	Y	Identical
M Mode	Y	Y	Identical
Pulse Wave Doppler	Y	Y	Identical
Indications			
Ophthalmic	N	N	Identical
Fetal	Y	Y	Identical
Abdominal	Y	Y	Identical
Intra-operative (Specify)	N	N	Identical
Intra-operative (Neuro)	N	N	Identical
Laparoscopic	N	N	Identical
Pediatric	Y	Y	Identical
Small Organ	Y	Y	Identical
Neonatal Cephalic	N	Y	No
Adult Cephalic	N	N	Identical
Trans-rectal	Y	Y	Identical
Trans-vaginal	Y	Y	Identical
Trans-urethral	N	N	Identical
Trans-esoph. (Non-Card.)	N	N	Identical
Musculo-skeletal (Conventional)	Y	Y	Identical

Musculo-skeletal (Superficial)	Y	Y	Identical
Intravascular	N	N	Identical
Cardiac Adult	Y	Y	Identical
Cardiac Pediatric	Y	Y	Identical
Intravascular (Cardiac)	N	N	Identical
Trans-esoph. (Cardiac)	N	N	Identical
Intra-cardiac	N	N	Identical
Gynecological	Y	Y	Identical
Peripheral Vessel	Y	Y	Identical
Urology (Including prostate)	Y	Y	Identical
Integrated Speaker	Y	Y	Identical
DICOM	N	Y	Identical

Summary of the Technological Characteristics of the Device Compared to the Predicate Device

The U-Lite EXP is comparable to the U-Lite (K143601) in technological characteristics and operating principle. The U-Lite EXP offers the advantage of exchangeable probes versus fixed probes of the predicate. Both devices transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have similar intended use and basic operating modes. Both systems allow for specialized measurements of structures and flow and calculations.

Performance Data:

The device has been evaluated for acoustic output, biocompatibility, as well as for thermal, electrical, electromagnetic and mechanical safety, and has been found to conform to applicable medical device safety standards. The U-Lite complies with the voluntary standards:

- EN ISO 13485:2012, EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

- EN 60601-1:2006 + A1:2013 Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:2005, IEC 60601-1:2005/A1:2012)

- EN 60601-1-1:2001 + A1:2006 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000)

- EN 60601-1-2:2007 + AC:2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))

- EN 60601-1-6:2010Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)

- EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007)

- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007)

- EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006)

- EN 62366:2008 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)

- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process(ISO 10993-1:2009)

- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)

- EN ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

- EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)

Clinical Study:

No clinical study was conducted.

Conclusion:

Based upon the testing and comparison to the predicate device, the Sonoscanner U-Lite EXP Diagnostic Ultrasound Device has similar intended use, identical technological characteristics and operating principle. The U-Lite EXP is substantially equivalent to the predicate U-Lite and does not raise any new safety and effectiveness issues.