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 SARL
% Mr. Frank Ferguson
CEO
Ferguson Medical International Device Consultants LLC
332 Laskin Road, Suite 437
VIRGINIA BEACH VA 23451

March 18, 2015

Re: K143601
Trade/Device Name: U-Lite
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 3, 2015
Received: February 5, 2015

Dear Mr. Ferguson:

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,

Robert A Ochs

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

Enclosure

INDICATIONS FOR USE

510(k) Number (If known): K143601

Device Name: U-Lite

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: fetal/obstetric, gynecological, abdominal, pediatric, small organ, trans-vaginal, trans-rectal, cardiac, peripheral vascular, urology, and musculoskeletal (both conventional and superficial).

Prescription Use ___XX___ (21 CFR 801 Subpart D)

OR

Over-The- Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Format

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U-Lite with Vl-1 Convex Array Transducer

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	

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

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

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Concurrence of CDRH

Diagnostic Ultrasound Indications for Use Format

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U-Lite with Vl-2 Phased Array Transducer

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	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	

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

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

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Concurrence of CDRH

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Format

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U-Lite with Vl-3 Linear Array Transducer

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	
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)									

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

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

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Concurrence of CDRH

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Format

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U-Lite with Vl-4 Endocavitary (Curved) Transducer

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									
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	

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

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

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Sonoscanner U-Lite Diagnostic Ultrasound Device.

DATE PREPARED: 12 December 2014

APPLICANTS NAME AND ADDRESS:

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DEVICE NAME:

Trade Name: U-Lite

Common Name: Ultrasound Scanner
Classification Name: System, Imaging, Pulsed Doppler Ultrasonic
Product Code:

Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer, 21CFR 892-1570, 90-ITX

LEGALLY MARKETED DEVICE TO WHICH SONOSCANNER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Device Name: Venue 50
510(k) Reference: (K133431)
Manufacturer: GE Healthcare

DEVICE DESCRIPTION:

U-Lite is a 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 to display the data as B Mode, M Mode, Color Mode, Power Doppler imaging, and Pulse Wave Doppler spectrum. The U-Lite device utilizes a standard range of probes, including curved array (convex), linear array, phased array (sector), and endocavitary transducers.

The handheld U-Lite 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 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.

INTENDED USE:

The Sonoscanner U-Lite ultrasound diagnostic device is intended for use by trained health care professionals (physician, sonographer, etc.) for diagnostic ultrasound imaging and fluid flow analysis of the human body. Utilizing curved, linear, phased array, and endocavitary probes, the U-Lite allows for a wide range of clinical applications: Fetal/obstetric, gynecological, abdominal, pediatric, small organ, trans-vaginal, trans-rectal, cardiac, peripheral vascular, and musculoskeletal.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE:

The U-Lite is of comparable type and substantially equivalent to the GE Venue 50 diagnostic ultrasound system (K133431). 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 the same 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 voluntary standards:

- IEC/EN 60601-1 Medical Electrical Equipment, Part 1 General Requirements for Safety
- IEC/EN 60601-1-1 Safety Requirements for Medical Electrical Systems
- IEC/EN 60601-1-2 Amendment A1:2006, General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC/EN 60601-1-6 General Requirements for Safety – Collateral Standard: Usability
- IEC/EN 60601-2-37 Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment

CONCLUSIONS:

Based upon the testing and comparison to the predicate device, the Sonoscanner U-Lite Diagnostic Ultrasound Device has the same intended use and similar technological characteristics. The device performs as intended and does not raise and new safety or effectiveness issues.