January 11, 2024

Sonoscanner SARL
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave.
CROFTON MD 21114

Re: K232285
Trade/Device Name: U-Lite PRO
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 11, 2023
Received: December 11, 2023

Dear Yolanda 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232285

Device Name
U Lite PRO

Indications for Use *(Describe)*
U-Lite PRO is a Handheld Ultrasound system intended for use in environments where healthcare is provided by qualified and trained healthcare professionals.
It can therefore be used in different configurations, especially:
- In medical offices (general practitioner's office)
- In clinics & hospitals (incl. in emergency and critical care units)
- In a field hospital

It is used in imaging or examinations rooms.
It can be used at the bedside. It is not intended for direct use in a sterile environment.
The U-Lite PRO is not compatible with the use of the HF surgery device or in an MRI system.

U-Lite PRO 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:
• ophthalmic
• fetal/obstetric,
• gynecological,
• abdominal,
• pediatric,
• neonatal cephalic
• adult cephalic
• small organ,
• trans-vaginal,
• trans-rectal,
• cardiac adult & pediatric
• peripheral vascular,
• urology (including prostate)
• musculoskeletal (both conventional and superficial)

Note : The application fields are dependent on the selected probes and the modes of operations.

Modes of operations include:
• B-Mode (B)
• M-Mode (M)
• Color Doppler (CD)
• Power Doppler (PD)
• Spectral Pulsed-Wave Doppler (PWD)
• Continous Wave Doppler (CWD)
• Combined :(B+M; B+CD; B+ PD; B+PWD)

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.

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

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K232285
510(k) Summary

1. SUBMITTER: Sonoscanner SARL

Address: 6, rue Andre Voguet
94200 Ivry Sur Seine
France

Contact Person : Vincent Lux
Quality Assurance & Regulatory Affairs Manager

Telephone: + 33 1 84 77 19 72

Email: qara@sonoscanner.com
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Date Prepared: January 4, 2023

2. DEVICE

Trade Name: U-Lite PRO

Classification Name: System, Imaging, Pulsed Doppler, Ultrasonic

Common Name: Ultrasonic Pulsed Doppler System

Regulation Number: 21 C.F.R. 892.1550

Product Code: IYN, IYO & ITX

Device Class: Class II

Classification Panel: Radiology

3. PREDICATE DEVICE

Predicate Devices:

	Manufacturer	Brand Name	510(k) Number
Primary Predicate	Sonoscanner	T Lite	K201988
Reference Predicate	Sonoscanner	U-Lite Exp	K171164
Reference Predicate	Edan Instruments, Inc.	Diagnostic Ultrasound System, Models: Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18, Acclarix LX3, Acclarix LX3 Exp, Acclarix LX3 Super, Acclarix LX25 and Acclarix LX28	K202856
Reference Predicate	GE Medical Systems Ultrasound and Primary Care Diagnostics	Vscan Air	K231301

4. DEVICE DESCRIPTION

Device Description:

U-Lite PRO is a compact, ultralight battery powered general purpose diagnostic ultrasound scanner. The U-Lite PRO is a notebook-size, battery-operated, general-purpose track 3 diagnostic ultrasound system. The U-Lite PRO can be handheld measuring 180mm x 115mm x 20mm and weighing 0.7 kg (approximately 1.54 lbs.). The unit is a handheld ultrasound (HHU) imaging system with interchangeable probes with optional stand.

The U-Lite PRO is used to acquire and display high-resolution LED screen images, real-time ultrasound data and display the data as B Mode, M Mode, PWD Mode, CWD Mode, Color Doppler Mode, Power Doppler, Tissue Harmonic Imaging Mode, and Combined (B +M; B+CD; B+PD; B+PWD).

5. INDICATIONS FOR USE

Indications for Use

U-Lite PRO is a Handheld Ultrasound system intended for use in environments where healthcare is provided by qualified and trained healthcare professionals.

It can therefore be used in different configurations, especially:

→ In medical offices (general practitioner's office)

→ In clinics & hospitals (incl. in emergency and critical care units)

→ In a field hospital

It is used in imaging or examinations rooms.
It can be used at the bedside. It is not intended for direct use in a sterile environment.

The U-Lite PRO is not compatible with the use of the HF surgery device or in an MRI system.

U-Lite PRO 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:

- ophthalmic
- fetal/obstetric,
- gynecological,
- abdominal,
- pediatric,
- neonatal cephalic
- adult cephalic
- small organ,
- trans-vaginal,
- trans-rectal,
- cardiac adult & pediatric
- peripheral vascular,
- urology (including prostate)
- musculoskeletal (both conventional and superficial)

Note : The application fields are dependent on the selected probes and the modes of operations.

Modes of operations include:
• B-Mode (B)
• M-Mode (M)
• Color Doppler (CD)
• Power Doppler (PD)
• Spectral Pulsed-Wave Doppler (PWD)

- Continous Wave Doppler (CWD)
- Combined :(B+M; B+CD; B+ PD; B+PWD)

6. APPLICATIONS

The applications fields are dependent on the selected probes and the modes of operations:

Transducer	Indications	Mode
PR50 Convex Probe	Fetal, abdominal, pediatric, musculo-skeletal (conventional), other (gynecological), Urology (including prostate)	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR51 Linear 40mm Probe	Ophthalmic, Pediatric, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR52 Linear 50mm Probe	Ophthalmic ,Pediatric, small organ (breast, testes, thyroid), musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR53 Endocavitary Probe	Fetal, trans-rectal, trans-vaginal, other (gynecological), urology (including prostate)	B, M, PWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler).

Transducer	Indications	Mode
PR54 Phased Array Probe	Fetal, abdominal, pediatric, Adult cephalic musculo-skeletal (conventional), cardiac adult, cardiac Pediatric, other (gynecological), urology (including prostate)	B, M, PWD, CWD, Color Doppler, Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR55 Microconvex Probe	Fetal, abdominal, small organ (breast, testes, thyroid, neonatal cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel, urology (including prostate)	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR56 Convex Probe Access	Fetal, abdominal, Pediatrics, musculo-skeletal (conventional), other (Gynecological), Urology	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR57 Linear Probe Access	Ophthalmic ,Pediatrics, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR58 Microconvex Probe	Fetal, abdominal, Pediatrics, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel, urology (including prostate)	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR59 Convex Probe Single Crystal	Fetal, abdominal, Pediatrics, musculo-skeletal (conventional), other (Gynecological), urology (including prostate)	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)
PR60 Hockey Stick Probe	Pediatrics, small organ (breast, testes, thyroid), Neonatal Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), Peripheral Vessel,	B, M, PWD, Color Doppler Power Doppler, Tissue Harmonic Imaging, Combined (B + Color Doppler)

7. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Predicate Comparison Table

Parameters	U Lite PRO Subject	T-Lite Primary	U-Lite EXP Reference	Vscan Air Reference	Acclarix AX3 Reference	Comment
510(k) Number		K201988	K171164	K231301	K202856	/
Manufacturer	Sonoscanner	Sonoscanner	Sonoscanner	GE Medical Systems	Edan Instruments	/
Regulation Numbers	21 CFR 892.1550 21 CFR 892.1560 21 CFR 893.1570	21 CFR 892.1550 21 CFR 892.1560 21 CFR 893.1570	21 CFR 892.1550 21 CFR 892.1560 21 CFR 893.1570	21 CFR 892.1550 21 CFR 892.1560 21 CFR 893.1570	21 CFR 892.1550 21 CFR 892.1560 21 CFR 893.1570	Same
Product Codes	IYN ITX IYO	IYN ITX IYO	IYN ITX IYO	IYN ITX IYO	IYN ITX IYO	Same

Parameters	U Lite PRO Subject	T-Lite Primary	U-Lite EXP Reference	Vscan Air Reference	Acclarix AX3 Reference	Comment
Indications for use	U-Lite PRO 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: • ophthalmic • fetal/obstetric, • gynecological, • abdominal, • pediatric, • neonatal cephalic • adult cephalic • small organ, • trans-vaginal, • trans-rectal, • cardiac adult & pediatric • peripheral vascular, • urology (including prostate) • musculoskel etal (both conventional and superficial) Note : The application fields are dependent on the selected probes and the modes of operations. Modes of operations include: • B-Mode (B) • M-Mode (M) • Color Doppler (CD) • Power Doppler (PD) • Spectral Pulsed-Wave Doppler (PWD) • Continous Wave Doppler (CWD) • Combined :(B+M; B+CD; B+ PD; B+PWD)	T-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 • Musculoskeletal (both conventional and superficial) • Neonatal cephalic	U-Lite EXP is indicated for the visualization of structures and dynamic processes in the human body using ultrasound imaging and fluid analysis for diagnosis in the following clinical applications: • Abdominal • Small parts • Vascular • Cardiac • Obstetrics • Gynecology • Fetal • Pediatrics	Vscan Air is enabling visualization and measurement of anatomical structures and fluid including blood flow. abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy). vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block, vascular access and biopsy).	The Acclarix AX3 series/Acclarix LX3 series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics. General clinical applications include: • Abdominal, • Gynecology, • Obstetric, • Cardiac, • Small parts, • Urology, • Musculoskeletal • Peripheral vascular, • Intra-operative, • Pediatric, • Neonatal , • Adult Cephalic.	/
Intended Use	Intended for diagnostic ultrasound analysis and fluid flow analysis	Intended for diagnostic ultrasound analysis and fluid flow analysis	Intended for diagnostic ultrasound analysis and fluid flow analysis	Intended for diagnostic ultrasound analysis and fluid flow analysis	Intended for diagnostic ultrasound analysis and fluid flow analysis	Same
Track	Track 3	Track 3	Track 3	Track 3	Track 3	Same

Parameters	U Lite PRO Subject	T-Lite Primary	U-Lite EXP Reference	Vscan Air Reference	Acclarix AX3 Reference	Comment
Dimensions	180 x 115 x 20 mm 7.09 x 4.53 x0.79''	253 x 174 x19mm 9.96 x 6.85x0.7"	190 x 135 x20mm 7.5 x 5.3 x0.8"	131 x 64 x 31 mm	375 ×380 ×58 mm	Different
Weight	1.4 lbs	2.20 lbs	1.8 lbs	0.45 lbs	9.92 lbs	Different
Configuration/ Design	Notebook, handheld	Notebook, handheld	Notebook, handheld	dual headed probes with app (mobile device)	Portable	Different
Battery Life	2 hours	3 hours	1hr 30mins	50 min.	2 hours	Different
Display Size	7 in	10.1in	7in	na	10.1 in	Different
Tabletop Docking	Yes	Yes	Yes	No	No	Same
Mobile Cart	Yes	Yes	Yes	No	Yes	Same
Scanning Modes						
B MODE	Y	Y	Y	Y	Y	Same
M MODE or TM-mode	Y	Y	Y	Y	Y	Same
HARMONIC	Y	Y	Y	Y	Y	Same
3D	N	N	N	N	N	Same
4D	N	N	N	N	N	Same
COLOR DOPPLER MODE	Y	Y	Y	Y	Y	Same
PULSE WAVE DOPPLER	Y	Y	Y	Y	Y	Same
CONTINUOUS WAVE DOPPLER	Y	N	N	N	Y	Same (Acclarix)
POWER DOPPLER	Y	Y	Y	Y	Y	Same
TISSUE DOPPLER	Y	Y	Y	Y	Y	Same
DIRECTIONAL POWER DOPPLER	Y	N	N	N	Y	Same (Acclarix)

Parameters	U Lite PRO Subject	T-Lite Primary	U-Lite EXP Reference	Vscan Air Reference	Acclarix AX3 Reference	Comment
BIOPSY ATTACHMENT	Y	Y	Y	Y	Y	Same
Indications						
Ophthalmic	Y	N	N	Y	N	Same
Fetal	Y	Y	Y	Y	Y	Same
Abdominal	Y	Y	Y	Y	Y	Same
Intra- operative (Specify)	N	N	N	N	Y	Same
Intra- operative (Neuro)	N	N	N	N	N	Same
Laparoscopic	N	N	N	N	N	Same
Pediatric	Y	Y	Y	Y	Y	Same
Small Organ	Y	Y	Y	Y	Y	Same
Neonatal Cephalic	Y	Y	Y	Y	Y	Same
Adult Cephalic	Y	N	N	Y	Y	Same (Vscan & Acclarix)
Trans-rectal	Y	Y	Y	Y	Y	Same
Trans-vaginal	Y	Y	Y	Y	Y	Same
Trans-urethral	N	N	N	N	N	Same
Trans-esoph. (Non-Card.)	N	N	N	N	N	Same
Musculo-skeletal (Conventional)	Y	Y	Y	Y	Y	Same
Musculo-skeletal (Superficial)	Y	Y	Y	Y	Y	Same
Intravascular	N	N	N	N	N	Same
Cardiac Adult	Y	Y	Y	N	Y	Same

Parameters	U Lite PRO Subject	T-Lite Primary	U-Lite EXP Reference	Vscan Air Reference	Acclarix AX3 Reference	Comment
Cardiac Pediatric	Y	Y	Y	N	Y	Same
Intravascular (Cardiac)	N	N	N	N	N	Same
Trans-esoph. (Cardiac)	N	N	N	N	N	Same
Intra-cardiac	N	N	N	N	N	Same
Gynecological	Y	Y	Y	Y	Y	Same
Peripheral Vessel	Y	Y	Y	Y	Y	Same
Urology (Including prostate)	Y	Y	Y	Y	Y	Same
Integrated Speaker	Y	Y	Y	Y	Y	Same
DICOM	Y	Y	Y	Y	Y	Same

Discussion of Technological Difference

The U-Lite PRO is comparable to primary predicate T-Lite (K201988) in technological characteristics and operating principle. It uses the same beamformer and the same exchangeable probes. 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.

The proposed U Lite PRO and T Lite (K201988) have the similar clinical intended use and clinical applications. However, the following clinical applications are added to the proposed U Lite PRO: Ophthalmic & Adult cephalic which can be found in the reference predicate, VScan Air (K231301).

Non-clinical performance testing showed that the subject device is as safe and effective as the predicate device.

For ophthalmic clinical applications

Acoustic output testing was conducted with PR51, PR52, and PR57 probes with "Ophthalmic" preset.

Results confirms that the maximum values for ophthalmic application are respected i.e

- ISPTA less than or equal to 50 mW/cm2
- MI less than or equal to 0.23
- TI=Max (TIS_as,TIC) as less than or equal to 1

Results confirms that the system complies with IEC 60601-2-37 standard

For adult cephalic clinical application

Acoustic output testing was conducted with PR54 probe to support the Transcranial Doppler Ultrasound (TCD) application in PW operating mode.

Results confirms that the maximum values (track 3) for adult cephalic application are respected i.e

- ISPTA less than or equal to 720 mW/cm2
- MI less than or equal to 1.9

Results confirms that the system complies with IEC 60601-2-37 standard

Modes and Transducers

The proposed U Lite PRO and the primary T Lite (K201988) support B-mode, B Mode, M Mode or TM-mode, Harmonic, Color Doppler Mode, Pulse Wave Doppler, Power Doppler, Tissue Doppler. In addition, the proposed U Lite PRO also supports Continuous Wave Doppler (CW) and Directional Power Doppler (DPD) modes which are cleared in the reference predicate, Acclarix AX3 (K202856).

The U Lite PRO comes with 11, previously cleared, exchangeable probes, PR50, PR51, PR52, PR53, PR54, PR55 PR56, PR57, PR58, PR59 PR60 (K171164 & K201988) which have been evaluated and found to be safe for the intended use of the device.

All these probes can be used with all U-Lite and T-Lite models.

All these probes were tested with the subject device in accordance with IEC 60601-2-37 standard and results do not raise any safety and performance issue.

Hardware

The hardware difference is to use one electronic component with faster CPU and faster GPU at the same power consumption, combined with more RAM, the new component can provide either more processing power for demanding applications, or lower average power consumption for the same processing tasks. The proposed change will therefore add Continuous – Wave (CW) Doppler interrogation methods to the modes of operation of the device.

The power supply of the U-Lite PRO is 15V DC similar to the predicate T Lite and batteries support operation for 2 hours continuous scanning.

Electrical safety and EMC testing were conducted on the U Lite PRO. The system complies with the IEC 60601-1 and IEC 60601-2-37 for safety and the IEC 60601-1-2 for EMC.

8. PERFORMANCE DATA

Non-Clinical Tests

The U Lite PRO was tested to EN 60601-1:2006+A1:2013+AC:2014+A12:2014+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 60601-1:2006 + A1:2013 Medical electrical equipment - Part 1: General requirements for safety and final report stated the U-Lite PRO complies with requirements of the test performed.

The U Lite PRO was tested to EN 60601-1-2:2015+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests and final report stated the U-Lite PRO complies with requirements of the test performed.

The differences between the U-Lite PRO versus the predicate does not raise any new safety issues

Nonclinical Performance Testing:

EN 60601-1:2006+A1:2013+AC:2014+A12:2014+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+AMD1:2012+AMD2:2020)

EN 60601-1-2:2015+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014+AMD1:2020)

EN 60601-1-6:2010+A1:2015+A2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010+AMD1:2013+AMD2:2020)

EN 60601-2-37:2008/A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2015)

EN ISO 14971:2019/A11:2021Medical devices - Application of risk management to medical devices (ISO 14971:2019)

EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes (IEC 62304:2006+AMD1:2015)

EN 62366-1:2015+AC:2015+AC:2016+A1:2020 Medical devices - Application of usability engineering to medical devices (IEC 62366-1:2015+AMD1:2020)

EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)

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)

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Summary of Testing:

Biocompatibility:

The proposed U Lite PRO transducers are the same as the primary predicate device T Lite already cleared (K201988) and materials are ISO 10993-1 compliant. The U Lite PRO probes are manufactured using the exact same material, suppliers and exact manufacturing processes as the U-Lite Probes cleared under (K171164) and T Lite Probes (K201988)

Software Verification & Validation:

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Acoustic Measurement Summaries

2D Measurement Range and Accuracy

Table 11.5 2D Measurement Range and Accuracy

Measurement	Accuracy	Range
Axial Distance	≤ ± 3%	0 - 30.0 cm
Lateral Distance	≤ ± 3%	0 - 30.0 cm
Diagonal Distance	≤ ± 3%	0 - 40.0 cm
Area	< ±7%	0.1-720 cm2
Circumference	< ±5%	0.1-96 cm
Contour	< ±5%	0.1-96 cm

M Mode Measurement and Accuracy

Table 11.6 M Mode Measurement and Accuracy

Measurement	Accuracy	Range
Distance	≤ ± 3%	30.0 cm
Time	≤ ± 2%	0.02 to >4.0 s

PW Mode Measurement and Accuracy

Table 11.7 PW & CW Mode Measurement and Accuracy

Measurement	Accuracy	Range
Velocity	≤ ± 12%	0.04 – 1.6 m/s
Time	≤ ± 2%	0.02 to >4.0 s

Clinical Studies:

No clinical studies were conducted.

9. CONCLUSIONS

Conclusion:

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