October 30, 2020

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

Re: K201988
Trade/Device Name: T-Lite
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 13, 2020
Received: October 14, 2020

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. 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/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 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 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201988

Device Name
T-Lite

Indications for Use *(Describe)*

The T-Lite ultrasound system is intended for use by an appropriately- trained healthcare professional. We recommend that all users receive proper training by an authorized Sonoscanner representative before attempting to use the scanner.
You must also follow corresponding local government rules and guidelines at all times.
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

NOTE : The application fields are dependent on the selected probe.

NOTE : T-Lite is a general-purpose ultrasound. It can therefore be used in different configurations, especially:
- in medical offices,
- in clinics,
- in hospitals.

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

NOTE : The T-Lite is not compatible with the use of the HF surgery device or in an MRI system.

Modes of operation include:

- B-Mode
- B-Mode + M-Mode
- B-Mode + Color Doppler
- B-Mode + Power Doppler
- Spectral Pulsed-Wave Doppler

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.

510(k) Summary

K201988

Sponsor:	Sonoscanner
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	France
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	Scientific Director, Quality Manager
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Summary Preparation Date: October 30, 2020

Device Name

Trade Name:	T-Lite
Common/Usual Name:	Ultrasonic Pulse Doppler Imaging System
Classification Name:	System, Imaging, Pulsed Doppler, Ultrasonic
Establishment:	3011688715
Registration Number	3011688715
Product Code:	IYN, IYO and ITX
Device Class:	Class II
Code of Federal Regulation:	21 CFR 892.1550, 21 CFR 892.1560 and 21 CFR 892.1570

Predicate Device:

	Manufacturer	Brand Name	510(k) Number
Primary Predicate	Sonoscanner	U-Lite Exp	K171164

Device Description:

T-Lite is a compact, ultralight, battery powered general purpose diagnostic ultrasound scanner. The T-Lite is a notebook-size, battery operated, general purpose track 3 diagnostic ultrasound

system. The T-Lite can be handheld measuring 253mm x 174mm x 19mm and weighing just 1kg (approximately 2.2lbs). The unit has a built-in kick stand or optional stand.

The T-Lite 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, Color Doppler Mode, Color Power Doppler, Duplex Mode, Tissue Harmonic Imaging Mode, Tissue Doppler and Combined (B + Color Doppler Mode).

Indications for Use:

The T-Lite ultrasound system is intended for use by an appropriately- trained healthcare professional. We recommend that all users receive proper training by an authorized Sonoscanner representative before attempting to use the scanner.

You must also follow corresponding local government rules and guidelines at all times.

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

NOTE: The application fields are dependent on the selected probe.

NOTE: T-Lite is a general-purpose ultrasound. It can therefore be used in different configurations, especially:

- in medical offices,
- in clinics,
- in hospitals.

It is used in imaging or examination rooms.

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

NOTE: The T-Lite is not compatible with the use of the HF surgery device or in an MRI system.

Modes of operation include:

- B-Mode
- B-Mode + M-Mode
- B-Mode + Color Doppler
- B-Mode + Power Doppler
- Spectral Pulsed-Wave Doppler

Predicate Product Comparison Table

Parameters	U-Lite EXP	T-Lite	Comment
510(k) Number	K171164		
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	Same
Product Codes	IYN ITX IYO	IYN ITX IYO	Same
Intended Use	Intended for diagnostic ultrasound analysis and fluid flow analysis	Intended for diagnostic ultrasound analysis and fluid flow analysis	Same
Track	Track 3	Track 3	Same
Dimensions	7.5 x 5.3 x 0.8 inches	253 x 174 x 19mm 9.96 x 6.85 x 0.7”	Different
Weight	1.8 lbs	2.20 lbs	Different
Configuration/Design	Notebook, handheld	Notebook, handheld	Same
Battery Life	1hr 30mins	3 hours	Different
Display Size	7in	10.1in	Different
Table Top Docking	Yes	Yes	Same
Mobile Cart	Yes	Yes	Same
Scanning Modes			
B Mode	Y	Y	Same
Color Mode	Y	Y	Same
Power Doppler	Y	Y	Same
M Mode	Y	Y	Same
Pulse Wave Doppler	Y	Y	Same

Parameters	U-Lite EXP	T-Lite	Comment
Indications			
Ophthalmic	N	N	Same
Fetal	Y	Y	Same
Abdominal	Y	Y	Same
Intra-operative (Specify)	N	N	Same
Intra-operative (Neuro)	N	N	Same
Laparoscopic	N	N	Same
Pediatric	Y	Y	Same
Small Organ	Y	Y	Same
Neonatal Cephalic	Y	Y	Same
Adult Cephalic	N	N	Same
Trans-rectal	Y	Y	Same
Trans-vaginal	Y	Y	Same
Trans-urethral	N	N	Same
Trans-esoph. (Non-Card.)	N	N	Same
Musculo-skeletal (Conventional)	Y	Y	Same
Musculo-skeletal (Superficial)	Y	Y	Same
Intravascular	N	N	Same
Cardiac Adult	Y	Y	Same
Cardiac Pediatric	Y	Y	Same
Intravascular (Cardiac)	N	N	Same
Trans-esoph. (Cardiac)	N	N	Same
Intra-cardiac	N	N	Same
Gynecological	Y	Y	Same
Peripheral Vessel	Y	Y	Same
Urology (Including prostate)	Y	Y	Same
Integrated Speaker	Y	Y	Same
DICOM	Y	Y	Same

Discussions of Technological Differences

The T-Lite is comparable to the predicate U-Lite-EXP(K171164) 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 T-Lite comes with 5 new exchangeable probes, PR56, PR57, PR58, PR59 PR60, in addition to the previously cleared probes PR50, PR51, PR52, PR53, PR54, PR55 (K171164). All these probes can be used with U-Lite and T-Lite models.

The differences are in the dimension and weight of the unit, the T-Lite offering a larger screen (10 inches vs 7 inches for the U-Lite) and a bigger battery (3 hours of function vs 1h30 hour for the U-Lite).

The power supply of the T-Lite is 15V DC vs 5V DC for the predicate U-Lite
The new direct current, power consumption and power adapter changes were tested to 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) standard and final report stated the T-Lite complies with requirements of the test performed.

The differences between the T-Lite versus the predicate does not raise any new safety issues.

Nonclinical Performance Testing:

- 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 60601-1-2:2015 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)
- EN 60601-1-6:2010 Medical 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/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 14971:2012 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 T-Lite Diagnostic Ultrasound Device has similar intended use, identical technological characteristics and operating principle. The T-Lite is substantially equivalent to the predicate U-Lite EXP and does not raise any new safety and effectiveness issues.