LELTEK Inc
% Kiefe Chang
Director
6F-3., No. 293, Sec. 1, Beixin Rd., Xindian Dist.,
New Taipei City, 23147
TAIWAN R.O.C.

February 12, 2020

Re: K191235
Trade/Device Name: Leltek Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO and ITX
Dated: December 31, 2019
Received: January 6, 2020

Dear Kiefe Chang:

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,

For

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)*
K191235

Device Name
Leltek Ultrasound Imaging System

Indications for Use *(Describe)*
The Leltek Ultrasound Imaging System (Model: LU700) is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. The device is intended for use in environments where healthcare is provided by trained healthcare professionals, but not intended for use in emergency medical service, ambulance, or aircraft.
Specific clinical applications and exam types including:
For LU700C:
General abdominal imaging, musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and OB/ Gyn. The modes of operation include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode(B+M, B+CD, B+PWD).
For LU700L:
General abdominal imaging, small organ (breast, thyroid), musculoskeletal (conventional), musculoskeletal (superficial) and peripheral vessel. The modes of operation includes B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode(B+M, B+CD, 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.

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System: Leltek Ultrasound Imaging System (Model: LU700)
Ultrasound Pulsed Echo System
Ultrasound Pulsed Doppler Imaging System
Scanner LU700C with Transducer: C2-5 Convex 3.6MHz Curved Linear Array Diagnostic Ultrasound Transducer.
Scanner LU700L with Transducer: L10-5 7.1MH Linear Array Diagnostic Ultrasound Transducer.
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	B+M, B+CD	
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Breast, Thyroid)	N	N	N		N	B+M, B+CD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculoskeletal (conventional)	N	N	N		N	B+M, B+CD	
	Musculoskeletal (superficial)	N	N	N		N	B+M, B+CD	
	Intravascular							
	Other (OB/Gyn.)	N	N	N		N	B+M, B+CD	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)							
Peripheral	Peripheral Vessel	N	N	N		N	B+M, B+CD	
Vessel	Other(Carotid)							

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

*The intended population is adults.

K191235

510(k) Summary

1. Submitter's Information

Manufacturer:	LELTEK Inc.
Address:	6F-3., No.293, Sec. 1, Beixin Rd., Xindian Dist., New Taipei City 23147, Taiwan, R.O.C.
Tel:	+886-2-2913-7577
Fax:	+886-2-2913-7599
Website:	www.leltek.com
Contact:	Kiefe Chang /Director
E-mail:	kiefe.chang@leltek.com
Name of Device:	Leltek Ultrasound Imaging System

2. Class and Predicate Information

Device Name:	Leltek Ultrasound Imaging System
Model:	LU700
Common Name:	Diagnostic Ultrasound System and Accessories
Classification:	Class II

Classification Name:

21 CRF Section	Classification Name	Product Code
892.1550	Ultrasonic Pulsed Doppler Imaging System	90 IYN
892.1560	Ultrasonic Pulsed Echo Imaging System	90 IYO
892.1570	Diagnostic Ultrasound Transducer	90 ITX

3. Substantially Equivalent Device

Device Name	510(k) Number
Clarius Ultrasound System	K172385

Reference Device

Device Name	510(k) Number
Clarius Ultrasound System	K163138

4. Indications for Use

The Leltek Ultrasound Imaging System (Model: LU700) is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation

by ultrasound imaging system or fluid flow analysis of the human body. The device is intended for use in environments where healthcare is provided by trained healthcare professionals, but not intended for use in emergency medical service, ambulance, or aircraft.
Specific clinical applications and exam types including:
For LU700C:
General abdominal imaging, musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and OB/Gyn. The modes of operation include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode(B+M, B+CD, B+PWD).
For LU700L:
General abdominal imaging, small organ (breast, thyroid), musculoskeletal (conventional), musculoskeletal (superficial) and peripheral vessel. The modes of operation includes B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode(B+M, B+CD, B+PWD).

5. Device description

The Leltek Ultrasound Imaging System is a portable, software controlled, handheld ultrasound system used to acquire and display hi-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) Android mobile device.

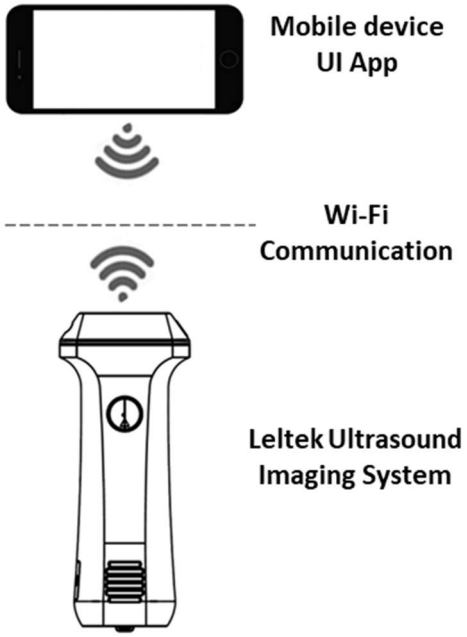
I. The imaging system software runs as an app on a mobile device.

II. The imaging system software can be download to a commercial off-the-shelf (COTS) Android mobile device and utilizes an icon touch-based user interface.

III. The imaging system consists of a series of wireless transducers employing Wi-Fi-based technology to communicate with traditional tablet/smartphone devices via direct Wi-Fi. This allows the user to export ultrasound images and display them across a range portable personal device.

IV. The imaging system houses a built-in battery, multichannel beamformer, prescan converter and Wi-Fi components

System drawing:


Mobile device
UI App
Wi-Fi
Communication
Leltek Ultrasound
Imaging System

6. Determination of Substantial Equivalence

Item	Application device	Predicate device	Reference device	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700)	Clarius Ultrasound Scanner	Clarius Ultrasound Scanner	-
510(k) Number	K191235	K172385	K163138	-
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Same
Indications for Use	- Abdominal - Small organ (Breast, Thyroid) - Musculoskeletal (conventional) - Musculoskeletal (superficial) - OB/Gyn - Peripheral Vessel	- Abdominal - Small organ - Musculoskeletal (conventional) - Musculoskeletal (superficial) - OB/Gyn - Peripheral vessel - Ophthalmic - Fetal - Intra-operative (nonneurological) - Pediatric - Adult Cephalic - Cardiac Adult - Cardiac Pediatric - Carotid - Procedural guidance of needles into the body.	- Abdominal - Small organ (Thyroid, scrotum, prostate, breast) - Musculoskeletal (conventional) - Musculoskeletal (superficial) - Urology, Gynecology - Peripheral Vessel - Fetal - Pediatric - Cardiac Adult - Cardiac Pediatric - Carotid	Different. Less items and without invasive subjects.
Mode of Operations	- B Mode - M mode - PWD - Color Doppler	- B Mode - M mode - Color Doppler	- B mode	Different. The device has Pulse Wave Doppler (PWD) mode as compared to the

Item	Application device	Predicate device	Reference device	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700)	Clarius Ultrasound Scanner	Clarius Ultrasound Scanner	-
	- Power Doppler - - - - Combined mode (B+M, B+CD, B+PWD)	- Power Doppler - - - - Combined mode (B+M, B+CD, B+PD)	- - - - -	predicate. The PWD mode is common in many ultrasound machines . The essential requirements are identical, and the proposed device has passed the tests.
Connect	Communicates wirelessly via Wi-Fi	Communicates wirelessly via Wi-Fi and Bluetooth	Communicates wirelessly via Wi-Fi and Bluetooth	Different. Both are wirelessly connected devices, whereas the application device uses only Wi-Fi as compared to the predicate.
Transducer Types	Linear array (LU700L) Convex array (LU700C)	Convex Array Linear Array Phased Array	Convex Array Linear Array	Different. Less transducers are provided with the application device.
Portability	Portable ultrasound system	Portable ultrasound system	Portable ultrasound system	Same
Power Source	Rechargeable battery (Li-ion)	Rechargeable battery (Li-ion)	Rechargeable battery (Li-ion)	Same
Display	Android mobile device	iOS or Android mobile device	iOS or Android mobile device	Different. Less for the application device .
510(k) Track	Track 3	Track 3	Track 3	Same
	- AAMI/ANSI ES60601-1 (2012)	- AAMI/ANSI ES60601-1 (2012)	- IEC 60601-1 (2012),	Different.

Item	Application device	Predicate device	Reference device	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700)	Clarius Ultrasound Scanner	Clarius Ultrasound Scanner	-
Compliance Standards	- IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - - IEC 60601-2-37 (2008) - AIUM/NEMA UD 2- 2004 R2009 - AIUM/NEMA UD 3- 2004 R2009 - IEC 62133 (2012) - IEC 62366 (2014) - ISO 10993-1(2009) - ISO 10993-5(2009) - ISO 10993-10(2010) - - IEC 62304 (2006) - ISO 15223-1 (2016) - ISO 14971 (2012) - ISO 13485 (2016)	- IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - IEC 60601-1-12 (2014) - IEC 60601-2-37 (2004) - NEMA UD2 (2009) - - IEC 62133 (2012) - IEC 62366 (2014) - ISO 10993-1 (2009) - ISO 10993-5 (2014) - ISO I0993-10(2014) - ISO 10993-12 (2014) - ISO 62304 (2006) - ISO 15223-1(2012) - ISO 14971 (2007) -	- IEC 60601-1-2 (2014) - - - IEC 60601-2-37 (2004) - NEMA UD2 (2009) - - - - ISO 10993-1 (2009) - - - - - - - - - ISO 14971 (2007) -	The application device does not claim its compliance with IEC60606-1-12 and ISO 10993-12 as compared to the predicate but can be compared to the reference device, which also excludes the emergency use. All the safety and performance tests meet the essential requirement to its intended use.

Based on the abovementioned SE table, the proposed device, Leltek Ultrasound Imaging system (Model: LU700), has the same intended use as the predicate devices. Nevertheless, the indications for use of the proposed device does not the same as the predicate device. The proposed device has less items, excludes the emergency use, and without invasive subjects. Thus, as all the safety and performance tests of the device meet the essential requirement, it does not affect the safety and effectiveness of the proposed device.

7. Performance standards

The Leltek Ultrasound Imaging System has been designed, manufactured, tested, and certified to comply with the following internationally recognized standards:

Reference No.	Year	Title
AAMI/ANSI/ES60601-1:2005/(R)2012 and A1:2012 and C1:2009/(R)2012 and A2:2010/(R)2012	2009 & 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6	2013	Medical electrical equipment Part 1-6 General requirements for basic safety and essential performance Collateral standard Usability
IEC 60601-2-37/AMD1	2008 & 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62133	2012	Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
IEC 62304	2014	Medical device software - Software life-cycle processes
EC 62366-1	2015	Medical devices -- Part 1: Application of usability engineering to medical devices
ISO 10993-1	2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971	2012	Medical devices - Application of risk management to medical devices

ISO 15223-1	2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Evaluation per standard AAMI/ANSI/ES60601-1 and IEC 60601-1-2 were performed for use of the transducers with a specific computer model (Panel PC Xiaomi/M1806D9W) and adaptor (FranMar, Model FRM06-S05) to charge the medical device. Use of alternate compatible computer hardware requires verification by the end user. Further information is provided in the user manual.

The Leltek Ultrasound Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as wireless, thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The Leltek Ultrasound Imaging System did not require clinical testing to establish substantial equivalence.

8. General Safety and Effectiveness

The differences between the proposed device, Leltek Ultrasound Imaging system and the predicate devices do not raise new questions of safety or effectiveness. Both of them meet FDA requirements for Track 3 devices, have biosafety equivalence, and conform to applicable electromedical devices safety standards. The intended use of both devices is the same whereas the differences all comply with the Food and Drug Administration's guidance. The Leltek Ultrasound Imaging System is designed for compliance to all applicable medical devices safety standards. Prior release for manufacturing, all such devices, so designed, are tested and determined to be in full compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness. No additional clinical testing is required. Maximum acoustic output level is under by the FDA recommended limit and power level is displayed all the time. The proposed device, Leltek Ultrasound Imaging system can be considered substantially equivalent to the listed predicate devices.

9. Conclusion

Verification and validation testing has been conducted on the Leltek Ultrasound Imaging System and ascertain that it is safe for use by physicians. This device is similar to an existing licensed device using technologies that exist on the market today. This premarket notification submission demonstrates that the Leltek Ultrasound Imaging System is substantially equivalent to the predicate device.