LELTEK, Inc.
% Jessie Wang
Chief of Marketing
6F-3., No. 293, Sec. 1, Beixin Rd., Xindian Dist.,
New Taipei City, 23147
TAIWAN, R.O.C

November 3, 2021

Re: K210432
Trade/Device Name: Leltek Ultrasound Imaging System (Model: LU700 Series)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 29, 2021
Received: Otober 4, 2021

Dear Jessie Wang:

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)*

K210432

Device Name
Leltek Ultrasound Imaging System (Model: LU700 Series)

Indications for Use *(Describe)*

The Leltek Ultrasound Imaging System (Model: LU700 Series) 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 clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients

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). Specific clinical applications and exam types including:

LU700C

General abdominal imaging, musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and OB/Gyn.

LU700L

General abdominal imaging, small organ (breast, thyroid), musculoskeletal (conventional), musculoskeletal (superficial) and peripheral vessel.

LU710C

Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional), urology, gynecology, cardiac adult, cardiac pediatric and peripheral vessel.

LU710M

Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional), urology, gynecology, cardiac adult, cardiac pediatric and peripheral vessel.

LU710PA

Fetal, abdominal, pediatric, cardiac adult, cardiac pediatric.

LU710E

Fetal, abdominal, small organ (thyroid, prostate, scrotum, breast), trans-rectal, trans-vaginal, urology, gynecology.

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.

K210432

510(k) Summary

1. Submitter's Information

Manufacturer:	LELTEK Inc.
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Tel:	+886-2-2913-7577
Fax:	+886-2-2913-7599
Website:	www.leltek.com
Contact:	Jessie wang / Chief of Marketing
E-mail:	jessie.wang@leltek.com
Name of Device:	Leltek Ultrasound Imaging System (Model: LU700 Series)

2. Class and Predicate Information

Device Name:	Leltek Ultrasound Imaging System
Model:	LU700 series
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 Devices

Device Name	510(k) Number
Leltek Ultrasound Imaging System	K191235

Reference Device

Device Name	510(k) Number
Clarius Ultrasound System	K192107

4. Indications for Use

The Leltek Ultrasound Imaging System (Model: LU700 Series) 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 clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients

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). Specific clinical applications and exam types including:

LU700C
General abdominal imaging, musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and OB/Gyn.

LU700L
General abdominal imaging, small organ (breast, thyroid), musculoskeletal (conventional), musculoskeletal (superficial) and peripheral vessel.

LU710C
Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional), urology, gynecology, cardiac adult, cardiac pediatric and peripheral vessel.

LU710M
Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional), urology, gynecology, cardiac adult, cardiac pediatric and peripheral vessel.

LU710PA
Fetal, abdominal, pediatric, cardiac adult, cardiac pediatric.

LU710E
Fetal, abdominal, small organ (thyroid, prostate, scrotum, breast), trans-rectal, trans-vaginal, urology, gynecology.

5. Device description

The Leltek Ultrasound Imaging System (Model: LU700 Series) 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) mobile device.

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

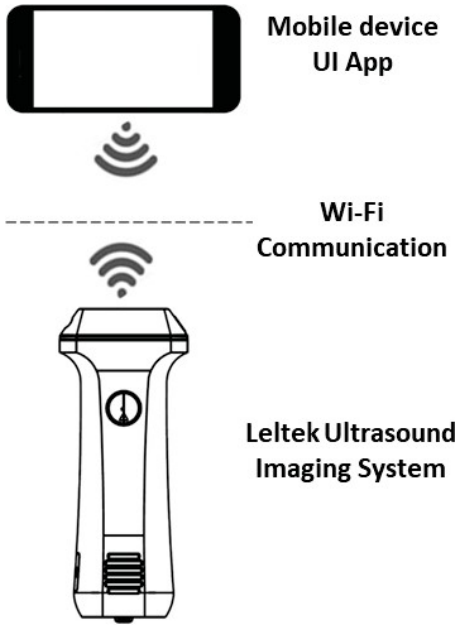
II. The imaging system software can be download to a commercial off-the-shelf (COTS) mobile device and utilizes an icon touch-based user interface.

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

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.

System drawing:



6. Determination of Substantial Equivalence

Item	Application device	Predicate device	Reference device	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700 series)	Leltek Ultrasound Imaging System (Model: LU700)	Clarius Ultrasound Scanner	-
510(k) Number	Current Submission	K191235	K192107	-
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	- - Fetal - Abdominal - - Pediatric - Small organ - - Trans-rectal - Trans-vaginal - Musculoskeletal(conventional) - Musculoskeletal (superficial) - Urology - OB/Gyn - Cardiac adult - Cardiac pediatric - Peripheral vessel - Carotid -	- - - Abdominal - - - Small organ - - - - Musculoskeletal(conventional) - Musculoskeletal (superficial) - - OB/Gyn - - - Peripheral vessel - -	- Ophthalmic - Fetal - Abdominal - Intraoperative (Ab/Vasc) - Pediatric - Small organ - Adult cephalic - Trans-rectal - Trans-vaginal - Musculo-skel. (Conv.) - Musculo-skel. (Superfic.) - Urology - Gynecology - Cardiac adult - Cardiac pediatric - Peripheral vessel - Carotid - Needle guidance	Different. LU700 series add more items including invasive subjects.
Mode of Operations	- B Mode - M mode - PWD - Color Doppler - Power Doppler	- B Mode - M mode - PWD - Color Doppler - Power Doppler	- B mode - M mode - PWD - Color Doppler - Power Doppler	Same.

Item	Application device	Predicate device	Reference device	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700 series)	Leltek Ultrasound Imaging System (Model: LU700)	Clarius Ultrasound Scanner	-
	- Combined mode (B+M, B+CD, B+PWD)	- Combined mode (B+M, B+CD, B+PWD)	- Combined mode (B+M, B+CD, B+PD, B+PWD)	
Connect	Communicates wirelessly via Wi-Fi	Communicates wirelessly via Wi-Fi	Communicates wirelessly via Wi-Fi and Bluetooth	Same
Transducer Types	Convex HD array (LU710C) MicroConvex array (LU710M) Phased array (LU710PA) Endocavity array (LU710E)	Linear array (LU700L) Convex array (LU700C)	Convex array Linear array Phased array Intracavity	More transducers are added to the LU700 series.
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	iOS or Android mobile device	iOS or Android mobile device	iOS or Android mobile device	Same
510(k) Track	Track 3	Track 3	Track 3	Same
Compliance Standards	- AAMI/ANSI ES60601-1 (2012) - 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)	- AAMI/ANSI ES60601-1 (2012) - 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)	- AAMI/ANSI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - IEC 60601-1-12 (2014) - IEC 60601-2-37 (2015) - UD 2- 2004 (R2009) - - IEC 62133 (2012)	Same. As compared to the predicate, the LU700 series comply with the safety and

Item	Application device	Predicate device	Reference device	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700 series)	Leltek Ultrasound Imaging System (Model: LU700)	Clarius Ultrasound Scanner	-
	- 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 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 62366 (2014) - ISO 10993-1 (2009) - ISO 10993-5 (2009) - ISO I0993-10 (2010) - ISO 10993-11 (2017) - ISO 62304 (2006) - ISO 15223-1 (2012) - ISO 14971 (2007) -	performance tests, which meets all the essential requirement for its intended use.

This device is a modification of an existing licensed device (K191235) using technologies that exist on the market as of the date of this submission. The Leltek Ultrasound Imaging System (Model: LU700 series) meets FDA requirements for Track 3 devices, have biosafety equivalence, and conform to applicable electromedical devices safety standards. The differences specified above have no pragmatic detriments. All the safety and performance tests of the device meet the essential requirements. Therefore, the system is substantially equivalent to predicate devices.

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 adaptor (Apple Model A1385) to charge the medical device. Use of alternate compatible mobile 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

This device is the addition of new transducer models to the Leltek Ultrasound Imaging System, using technologies existing on the market as of the date of this submission. The Leltek Ultrasound Imaging System (Model: LU700 series) meets FDA requirements for Track 3 devices, have biosafety equivalence, and conform to applicable electromedical devices safety standards.

The new models comprise LU710C, LU710M, LU710PA, LU710E, which are tested and determined to be in full compliance with acoustic output, biocompatibility, cleaning, and disinfection effectiveness, and have no pragmatic detriments. No additional clinical testing is required. The maximum acoustic output level is under the FDA recommended limit, and the power level is displayed all the time. All the safety and performance tests of the device meet the essential requirements. Therefore, the system is substantially equivalent to predicate devices.

9. Conclusion

Verification and validation testing have been conducted on the Leltek Ultrasound Imaging System and ascertain that it is safe for use by physicians. The 510(k) submission is the modification of the existing licensed device using technologies that exist on the market today and demonstrating the new transducers of the Leltek Ultrasound Imaging System are substantially equivalent in safety and effectiveness to the predicate device.