October 25, 2022

Leltek, Inc.
℅ Paul Chang
Manager
6F.-3, No. 293, Sec. 1, Beixin Rd., Xindian Dist.,
New Taipei City, Taiwan 23147
REPUBLIC OF CHINA

Re: K222365
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: August 4, 2022
Received: August 4, 2022

Dear Paul 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 and Part 809); 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222365

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 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:
LU700L
General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Musculoskeletal (conventional),Musculoskeletal (superficial),Peripheral vessel ,Other (Carotid),Pulmonary,interventional guidance (free hand needle/ catheter)
LU710L
Ophthalmic,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Musculoskeletal (conventional),Musculoskeletal (superficial),Peripheral vessel ,Other (Carotid),Pulmonary,interventional guidance (free hand needle/ catheter)
LU710LH
Ophthalmic,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Musculoskeletal (conventional),Musculoskeletal (superficial),Peripheral vessel ,Other (Carotid),Pulmonary,interventional guidance (free hand needle/ catheter)
LU700C
General abdominal imaging,Musculoskeletal (conventional),Musculoskeletal (superficial),OB/Gyn,Peripheral vessel ,interventional guidance (free hand needle/ catheter)
LU710C
Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Urology,Musculoskeletal (conventional),OB/Gyn,Cardiac (adult),Cardiac (pediatric),Peripheral vessel ,interventional guidance (free hand needle/ catheter)
LU710M
Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Urology,Musculoskeletal (conventional),OB/Gyn,Cardiac (adult),Cardiac (pediatric),Peripheral vessel ,interventional guidance (free hand needle/ catheter)
LU710PA
Fetal,General abdominal imaging,Pediatric,Cardiac (adult),Cardiac (pediatric),Pulmonary
LU710E
Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Trans-rectal,Trans-vaginal,Urology,OB/Gyn,interventional guidance (free hand needle/ catheter)

The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients.

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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510(k) Summary:
K222365

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:	Paul Chang/Manager
E-mail:	paul.chang@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	K210432

Reference Device

Device Name	510(k) Number
" GE" Vscan Air	K202035

4. Reason for Submission

Following changes have been made compared to the cleared device (Predicate Device #1)

- Wi-Fi module changed to support both 2.4 GHz & 5GHz connectivity
- New transducer added to the LU700 series: The LU710L, LU710LH with new transducer which can apply to the same main board of the 700 series.
- New clinical application added: Ophthalmic, Neonatal cephalic, Pulmonary and interventional guidance (free hand needle/ catheter)
- Software (Mobile application) Changes: Windows 10 support.
- Label Changes: Device label, Box label, User Manual

5. 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 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:

LU700L

General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Musculoskeletal (conventional),Musculoskeletal (superficial),Peripheral vessel ,Other (Carotid),Pulmonary,interventional guidance (free hand needle/ catheter)

LU710L

Ophthalmic,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Musculoskeletal (conventional),Musculoskeletal (superficial),Peripheral vessel ,Other (Carotid),Pulmonary,interventional guidance (free hand needle/ catheter)

LU710LH

Ophthalmic,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Musculoskeletal (conventional),Musculoskeletal (superficial),Peripheral vessel ,Other (Carotid),Pulmonary,interventional guidance (free hand needle/ catheter)

LU700C

General abdominal imaging,Musculoskeletal (conventional),Musculoskeletal (superficial),OB/Gyn,Peripheral vessel ,interventional guidance (free hand needle/ catheter)

LU710C

Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Urology,Musculoskeletal (conventional),OB/Gyn,Cardiac (adult),Cardiac (pediatric),Peripheral vessel ,interventional guidance (free hand needle/ catheter)

LU710M

Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Urology,Musculoskeletal (conventional),OB/Gyn,Cardiac (adult),Cardiac (pediatric),Peripheral vessel ,interventional guidance (free hand needle/ catheter)
LU710PA
Fetal,General abdominal imaging,Pediatric,Cardiac (adult),Cardiac (pediatric),Pulmonary
LU710E
Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Trans-rectal,Trans-vaginal,Urology,OB/Gyn,interventional guidance (free hand needle/ catheter)

The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients.

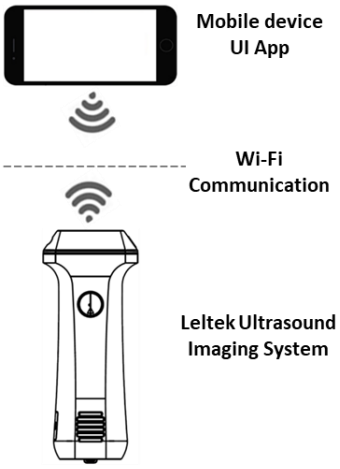
6. Device description

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.

7. Determination of Substantial Equivalence

Item	Application device	Primary Predicate device #1	Reference Device #2	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700 series)	Leltek Ultrasound Imaging System (Model: LU700 series)	Vscan Air	-
510(k) Number	Current Submission	K210432	K202035	-
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	- Ophthalmic - Fetal - Abdominal - - Pediatric - Small organ - - Neonatal cephalic - Trans-rectal - Trans-vaginal - Musculoskeletal(conventional) - Musculoskeletal (superficial) - Urology - OB/Gyn - Cardiac adult - Cardiac pediatric - Peripheral vessel - Carotid - - Pulmonary - interventional guidance (includes free hand needle/ catheter)	- - Fetal - Abdominal - - Pediatric - Small organ - - - Trans-rectal - Trans-vaginal - Musculoskeletal(conventional) - Musculoskeletal (superficial) - Urology - OB/Gyn - Cardiac adult - Cardiac pediatric - Peripheral vessel - Carotid -	With the curved array transducer of the dual headed probe solution, the specific clinical applications and exam types include: - 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). With the linear array transducer of the dual headed probe solution, the specific clinical applications and exam types include: - 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).	More intended purpose than the Primary Predicate device which referred to the reference device
Mode of Operations	- B Mode (Ophthalmic and others) - M mode - Pulsed wave Doppler (PWD)	- B Mode - M mode - PWD	- B mode - -	Same.

Item	Application device	Primary Predicate device #1	Reference Device #2	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700 series)	Leltek Ultrasound Imaging System (Model: LU700 series)	Vscan Air	-
	- Color Doppler(CF) - Power Doppler(PD) - Combined mode (B+M, B+CF, B+PWD)	- Color Doppler - Power Doppler - Combined mode (B+M, B+CF, B+PWD)	- Color Doppler - - Combined mode (B+CF)	
Connect	Communicates wirelessly via Wi-Fi	Communicates wirelessly via Wi-Fi	Communicates wirelessly via Wi-Fi and Bluetooth	Same
Transducer Types	Linear (LU700L, LU710L) Linear HD (LU710H) Convex HD array (LU700C,LU710C) MicroConvex array (LU710M) Phased array (LU710PA) Endocavity array (LU710E)	Linear (LU700L) Convex HD array (LU700C,LU710C) MicroConvex array (LU710M) Phased array (LU710PA) Endocavity array (LU710E)	Convex array Linear array	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 and Windows	iOS or Android mobile device	iOS or Android mobile device	Windows App added
Wireless Networking	IEEE 802.11 a/b/g/n	IEEE 802.11 b/g/n	--	5G WiFi added
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 (2015)	- AAMI/ANSI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - IEC 60601-2-37 (2008)	- IEC60601-1 - IEC 60601-1-2 - IEC 60601-1-6 (2013) - IEC 60601-1-11 - IEC 60601-1-12 (2014) - IEC 60601-2-37 (2015) -	Same. As compared to the predicate, the LU700 series

Item	Application device	Primary Predicate device #1	Reference Device #2	Comparison
Device name	Leltek Ultrasound Imaging System (Model: LU700 series)	Leltek Ultrasound Imaging System (Model: LU700 series)	Vscan Air	-
	- 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 (2019) - ISO 13485 (2016)	- 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)	- - - ISO 10993-1 - - - - ISO 62304 - ISO 15223-1 - ISO 14971 -	comply with the safety and performance tests, which meets all the essential requirement for its intended use.

This device is a modification of an existing licensed device (K210432) 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.

8. 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
IEC 62366-1	2015	Medical devices -- Part 1: Application of usability engineering to medical devices
ISO 10993-1	2009 & 2018	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	2019	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 (Model A1385) 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.

9. 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 LU710L, LU710LH, 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.

10. 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.