September 11, 2024

Leltek Inc.
Paul Chang
Manager
6F.-3, No.293, Sec 1, Beixin Rd., Xindian Dist.,
New Taipei City, 23147
TAIWAN

Re: K241161
Trade/Device Name: Ultrasound Imaging System (LK128L); Ultrasound Imaging System (LK128LH); Ultrasound Imaging System (LK128C); Ultrasound Imaging System (LK128M); Ultrasound Imaging System (LK128PA); Ultrasound Imaging System (LK128E); Ultrasound Imaging System (LU700C); Ultrasound Imaging System (LU700L); Ultrasound Imaging System (LU710L); Ultrasound Imaging System (LU710LH); Ultrasound Imaging System (LU710C); Ultrasound Imaging System (LU710M); Ultrasound Imaging System (LU710PA); Ultrasound Imaging System (LU710E)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 12, 2024
Received: August 12, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241161

Device Name

Ultrasound Imaging System (LK128L);
Ultrasound Imaging System (LK128LH)
Ultrasound Imaging System (LK128C);
Ultrasound Imaging System (LK128M);
Ultrasound Imaging System (LK128PA);
Ultrasound Imaging System (LK128E);
Ultrasound Imaging System (LU700C);
Ultrasound Imaging System (LU700L);
Ultrasound Imaging System (LU710L);
Ultrasound Imaging System (LU710LH);
Ultrasound Imaging System (LU710C);
Ultrasound Imaging System (LU710M);
Ultrasound Imaging System (LU710PA);
Ultrasound Imaging System (LU710E)

Indications for Use *(Describe)*

The Ultrasound Imaging System (Model: 128 Series) and (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:

LK128C

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),FAST/ EFAST,Nerve

LK128L

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),Nerve

LK128LH

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),Nerve

LK128M

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)

LK128PA

Fetal,General abdominal imaging,Pediatric,Cardiac (adult),Cardiac (pediatric),Pulmonary,FAST/ EFAST,Nerve

LK128E

Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Trans-rectal,Trans-vaginal,Urology,OB/Gyn,interventional guidance (free hand needle/ catheter) 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),Nerve
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),Nerve
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),Nerve
LU700C
General abdominal imaging,Musculoskeletal (conventional),Musculoskeletal (superficial),OB/Gyn,Peripheral vessel ,interventional guidance (free hand needle/ catheter),FAST/EFAST,Nerve
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),FAST/EFAST,Nerve
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,FAST/EFAST,Nerve
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 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.

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

K241161

1. Submitter's Information

Manufacturer: Leltek Inc.
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Name of Device:
Ultrasound Imaging System (LK128L);
Ultrasound Imaging System (LK128LH)
Ultrasound Imaging System (LK128C);
Ultrasound Imaging System (LK128M);
Ultrasound Imaging System (LK128PA);
Ultrasound Imaging System (LK128E);
Ultrasound Imaging System (LU700C);
Ultrasound Imaging System (LU700L);
Ultrasound Imaging System (LU710L);
Ultrasound Imaging System (LU710LH);
Ultrasound Imaging System (LU710C);
Ultrasound Imaging System (LU710M);
Ultrasound Imaging System (LU710PA);
Ultrasound Imaging System (LU710E)

2. Class Information

Date: 2024/09/10
Device Name: Ultrasound Imaging System
Proprietary Name: LU700 Series, 128 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

Primary Predicate Device

Device Name	510(k) Number
"Leltek" Ultrasound Imaging System	K222365

Reference Device

Device Name	510(k) Number
Aco Apache Ultrasound System	K231509

4. Reason for Submission

- Add new specific clinical applications: FAST/EFAST, Nerve
- Add new transducer: LK128C, LK128L, LK128LH, LK128M, LK128PA, LK128E.

5. Indications for Use

The Ultrasound Imaging System 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:

LK128C

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),FAST/EFAST,Nerve

LK128L

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),Nerve

LK128LH

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),Nerve

LK128M

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)

LK128PA

Fetal,General abdominal imaging,Pediatric,Cardiac (adult),Cardiac (pediatric),Pulmonary,FAST/EFAST,Nerve

LK128E

Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Trans-rectal,Trans-vaginal,Urology,OB/Gyn,interventional guidance (free hand needle/ catheter)

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),Nerve

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),Nerve
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),Nerve
LU700C
General abdominal imaging,Musculoskeletal (conventional),Musculoskeletal (superficial),OB/Gyn,Peripheral vessel ,interventional guidance (free hand needle/ catheter),FAST/EFAST,Nerve
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),FAST/EFAST,Nerve
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,FAST/EFAST,Nerve
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 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.

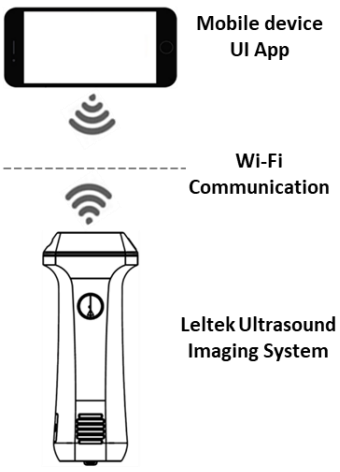
6. Device description

The 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) 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

7. Determination of Substantial Equivalence

Item	Application device	Primary Predicate	Reference Device	Comparison
Device name	Ultrasound Imaging System (Model: 128 series)	Ultrasound Imaging System (Model: LU700 series)	Aco Apache Ultrasound System	-
510(k) Number	Current Submission	K222365	K231509	-
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	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) - FAST/EFAST, - Nerve, -	- 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) -	- Ocular - Fetal / Fetal Echo - Abdominal, - - Pediatric, - Small Organ (including breast, scrotum, thyroid), - - - - Musculo-skeletal (conventional - Musculo-skeletal (superficial) - Urology, - Obstetric/ Gynecological, - Cephalic (adult), - - Peripheral Vessel, - Carotid, - - Lung, - Needle Guidance - - FAST/EFAST, - Nerve,	Different. 128 series add more clinical applications.
Mode of Operations	- B Mode (Ophthalmic and others) - M mode - Pulsed wave Doppler (PWD)	- B Mode (Ophthalmic and others) - M mode - Pulsed wave Doppler (PWD)	B Mode M mode Pulsed wave Doppler (PWD)	Same.

Item	Application device	Primary Predicate	Reference Device	Comparison
Device name	Ultrasound Imaging System (Model: 128 series)	Ultrasound Imaging System (Model: LU700 series)	Aco Apache Ultrasound System	-
	- Color flow Doppler(CF / CD) - Power Doppler(PD) - Combined mode (B+M, B+CF, B+PWD) -	- Color flow Doppler(CF / CD) - Power Doppler(PD) Combined mode (B+M, B+CF, B+PWD) -	Color Doppler(CD) Power Doppler(PD) Combined mode (B+M, B+CD, B+PWD)	
Connect	Wireless communication via IEEE 802.11 a/b/g/n	Wireless communication via IEEE 802.11 a/b/g/n	Wireless communication via IEEE 802.11g/n	Same
Transducer Types	Linear (LK128L, LK128LH LU700L,LU710L, LU710LH) Convex array (LK128C, LU700C,LU710C) MicroConvex array (LK128M, LU710M Phased array (LK128PA, LU710PA) Endocavity array (LK128E, LU710E)	Linear (LU700L,LU710L,LU710LH) Convex array (LU700C,LU710C) MicroConvex array (LU710M) Phased array (LU710PA) Endocavity array (LU710E)	Linear array Convex array	More transducers are added to the 128 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 or OTC	iOS, Android mobile device or Windows	iOS, Android mobile device or Windows	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)	- AAMI/ANSI ES60601-1 (2012) - - IEC 60601-1-2 (2014)	- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 - ANSI/AAMI IEC 60601-1-2:2014	Same.

Item	Application device	Primary Predicate	Reference Device	Comparison
Device name	Ultrasound Imaging System (Model: 128 series)	Ultrasound Imaging System (Model: LU700 series)	Aco Apache Ultrasound System	-
	- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 - IEC60601-1-12 Edition 1.1 2020-07 - IEC 60601-2-37 (2015) - AIUM/NEMA UD 2- 2004 R2009 - AIUM/NEMA UD 3- 2004 R2009 - IEC 62133-2:2017+ AMD1:2021 IEC 62366 (2014) - ISO 10993-1:2018 - ISO 10993-5(2009) - ISO 10993-10:2021 - ISO 10993-23(2021) - IEC 62304:2006+ AMD1:2015 - ISO 15223-1 Fourth edition 2021-07 - ISO 14971 (2019) - ISO 13485 (2016)	- IEC 60601-1-6 (2013) - IEC 60601-2-37 (2015) - AIUM/NEMA UD 2- 2004 R2009 - AIUM/NEMA UD 3- 2004 R2009 - IEC 62133 (2012) - IEC 62366 (2014) - ISO 10993-1:2018 - ISO 10993-5(2009) - ISO 10993-10(2010) - - IEC 62304 (2006) - ISO 15223-1 (2016) - ISO 14971 (2012) - ISO 13485 (2016)	- IEC 60601-1-6:2010 +AMD1:2013+AMD2:2020 - - - - IEC 60601-2-37:2007+ AMD1:2015 - AIUM/NEMA UD 2- 2004 R2009 - - ISO 10993-1:2018 - - ISO 62304 - ISO 15223-1 - ISO 14971	As compared to the predicate, the 128 series 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 cleared device (K222365) using technologies that exist on the market as of the date of this submission. The Leltek Ultrasound Imaging System (Model: 128 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 the primary predicate device.

8. Performance standards

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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number/Date	Title of Standard
05/30/2022	19-46	ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
12/21/2020	19-36	ANSI AAMI IEC	60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
12/21/2020	5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
12/21/2020	19-38	IEC	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
06/27/2016	12-293	IEC	60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
12/23/2019	19-33	IEC	62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems
01/14/2019	13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
07/06/2020	5-129	ANSI AAMI IEC	62366-1:2015+AMD1:2020 (Consolidated Text)	Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
01/14/2019	2-258	ISO	10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
12/23/2016	2-245	ISO	10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
12/19/2022	2-296	ISO	10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
06/07/2021	2-291	ISO	10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
12/20/2021	5-134	ISO	15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
12/23/2019	5-125	ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices

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: 128 Series) and (Model: LU700 Series) meets FDA requirements for Track 3 devices, have biosafety equivalence, and conform to applicable electromedical devices safety standards.
The new models 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 the primary predicate device.

10. Conclusion

With increased clinical experience and imaging, additional clinical applications such as FAST/EFAST and Nerve diagnosis have been identified by clinics, which can be added to the existing legally marketed LU700 series device (K222365). Furthermore, the Leltek Ultrasound Imaging System (Model: 128 series) utilizes the same software and hardware architecture and transducer specifications as the LU700 series but replaces the cover material with plastic and features a smaller PCBA with same block diagram.

Pre-clinical test outcomes provide evidence that both the LU700 series and 128 series models meet FDA requirements for Track 3 devices, exhibit biosafety equivalence, and conform to applicable electromedical device safety standards. The specified differences have no pragmatic detriments. All safety and performance tests of the device meet essential requirements. Therefore, the system is considered substantially equivalent to the primary predicate device