December 04, 2025

ASUSTek Computer INC.
Andy Wu
Official Correspondent
No. 15, Lide Rd., Beitou Dist
Taipei, 112
TAIWAN

Re: K250791
Trade/Device Name: ASUS Ultrasound Imaging System (LU800 series)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 6, 2025
Received: November 6, 2025

Dear Andy Wu:

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,

MARJAN NABILI -S for

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.*

510(k) Number *(if known)*
K250791

Device Name
ASUS Ultrasound Imaging System (Model: LU800 series)

Indications for Use *(Describe)*
The ASUS Ultrasound Imaging System (Model: LU800 Series) is a software-based imaging system and accessories intended for use by qualified and trained 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:

LU800L
General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Neonatal cephalic, Musculoskeletal (conventional), Musculoskeletal (superficial), Peripheral vessel , Other(Carotid), Pulmonary, interventional guidance(includes free hand needle/ catheter)
LU800C
Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Urology, Musculoskeletal (conventional), OB/Gyn, Cardiac (adult), Cardiac(pediatric), Peripheral vessel, interventional guidance(includes free hand needle/ catheter)
LU800M
Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Neonatal cephalic, Urology, Musculoskeletal (conventional), OB/Gyn, Cardiac(adult), Cardiac (pediatric), Peripheral vessel
LU800PA
Fetal, General abdominal imaging, Pediatric, Cardiac (adult), Cardiac (pediatric), Pulmonary
LU800E
Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Trans-rectal, Trans-vaginal, Urology, OB/Gyn, interventional guidance(includes 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary: K250791

## 1. Submitter's Information


| | |
|---|---|
| Applicant: | ASUSTEK COMPUTER INCORPORATION |
| Address: | 1 F., No. 15, Lide Rd., Beitou Dist., Taipei City 112, |
| (R.O.C.) | Taiwan |
| Tel: | (886)2-28943447 #28203 |
| Fax: | (886)-2-2893-1687 #28203 |
| Website: | https://www.asus.com/ |
| Contact: | Andy Wu |
| E-mail: | andy5_wu@asus.com |
| Name of Device: | ASUS Ultrasound Imaging System (Model: LU800 Series) |


## 2. Class and Predicate Information

| | |
|---|---|
| Device Name: | ASUS Ultrasound Imaging System |
| Model: | LU800 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

| Predicate Device | Product Code |
|---|---|
| "Leltek" Ultrasound Imaging System(K222365) | 90 ITX<br>90 IYO<br>90 IYN |

| Reference Device | |
|---|---|
| " GE" Vscan Air( K202035 ) | 90 ITX<br>90 IYO<br>90 IYN |

## 4. Reason for Submission

First Ultrasound Imaging System of ASUS

## 5. Indications for Use

The ASUS Ultrasound Imaging System (Model: LU800 Series) is a software-based imaging system and accessories intended for use by qualified and trained 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:

LU800L
General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Neonatal cephalic, Musculoskeletal (conventional), Musculoskeletal (superficial), Peripheral vessel , Other(Carotid), Pulmonary, interventional guidance(includes free hand needle/ catheter)

LU800C
Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Urology, Musculoskeletal (conventional), OB/Gyn, Cardiac (adult), Cardiac(pediatric), Peripheral vessel, interventional guidance(includes free hand needle/ catheter)

LU800M
Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Neonatal cephalic, Urology, Musculoskeletal (conventional), OB/Gyn, Cardiac(adult), Cardiac (pediatric), Peripheral vessel

LU800PA
Fetal, General abdominal imaging, Pediatric, Cardiac (adult), Cardiac (pediatric), Pulmonary

LU800E
Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast), Trans-rectal, Trans-vaginal, Urology, OB/Gyn, interventional guidance(includes 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.

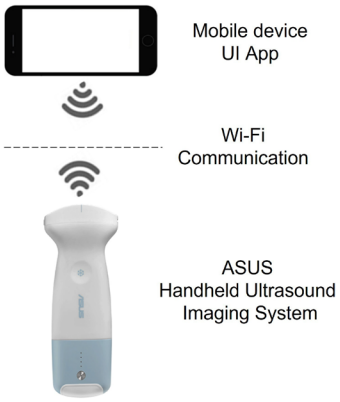
## 6. Device description

The ASUS Ultrasound Imaging System (Model: LU800 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 qualified and trained healthcare professionals, but not intended for use in emergency medical service, ambulance, or aircraft.

Technology:

The ASUS Ultrasound Imaging System (Model: LU800 Series) employs the same fundamental scientific technology as its predicate and reference devices.

## 7. Determination of Substantial Equivalence

| Item | Application device | Predicate device | Reference Device | Comparison |
|---|---|---|---|---|
| Device name | ASUS Ultrasound Imaging System (Model: LU800 series) | Leltek Ultrasound Imaging System (Model: LU700 series) | Vscan Air | - |
| 510(k) Number | K250791 | K222365 | 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 | - Fetal<br>- Abdominal<br>- Pediatric<br>- Small organ<br>- Neonatal cephalic<br>- Trans-rectal<br>- Trans-vaginal<br>- Musculoskeletal (conventional)<br>- Musculoskeletal (superficial)<br>- Urology<br>- OB/Gyn<br>- Cardiac adult<br>- Cardiac pediatric<br>- Peripheral vessel<br>- Carotid<br>- Pulmonary<br>- interventional guidance (includes free hand needle/ catheter) | - Ophthalmic<br>- Fetal<br>- Abdominal<br>- Pediatric<br>- Small organ<br>- Neonatal cephalic<br>- Trans-rectal<br>- Trans-vaginal<br>- Musculoskeletal(conventional)<br>- Musculoskeletal (superficial)<br>- Urology<br>- OB/Gyn<br>- Cardiac adult<br>- Cardiac pediatric<br>- Peripheral vessel<br>- Carotid<br>- Pulmonary<br>- interventional guidance (includes free hand needle/ catheter) | With the curved array transducer of the dual headed probe solution, the specific clinical applications and exam types include:<br>- abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung,<br>- cardiac (adult and pediatric, 40 kg and above), vascular/peripheral<br>- vascular, musculoskeletal (conventional), pediatrics,<br>- interventional guidance (includes free hand needle/ catheter<br>- placement, fluid drainage, nerve block and biopsy).<br>With the linear array transducer of the dual headed probe solution, the specific clinical applications and exam types include:<br>- vascular/peripheral vascular, musculoskeletal (conventional and<br>- superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand<br>- needle/catheter placement, fluid drainage, nerve block, vascular<br>- access and biopsy). | LU800 excluded indication in Ophthalmic |
| Mode of Operations | - B Mode<br>- M mode<br>- Pulsed wave Doppler (PWD) | - B Mode (Ophthalmic and others)<br>- M mode<br>- Pulsed wave Doppler (PWD) | - B mode<br>-<br>- | Same. |

| Item | Application device | Predicate device | Reference Device | Comparison |
|---|---|---|---|---|
| Device name | ASUS Ultrasound Imaging System (Model: LU800 series) | Leltek Ultrasound Imaging System (Model: LU700 series) | Vscan Air | - |
| | - Color Doppler(CF)<br>- Power Doppler(PD)<br>- Combined mode (B+M, B+CF, B+PWD)<br>- | - Color Doppler(CF)<br>- Power Doppler(PD)<br>Combined mode (B+M, B+CF, B+PWD)<br>- | - Color Doppler<br>-<br>- 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 (LU800L)<br>Convex HD array (LU800C)<br>MicroConvex array (LU800M)<br>Phased array (LU800PA)<br>Endocavity array (LU800E) | Linear (LU700L,LU710L,LU710LH)<br>Convex HD array (LU700C,LU710C)<br>MicroConvex array (LU710M)<br>Phased array (LU710PA)<br>Endocavity array (LU710E) | Convex array<br>Linear array | Same |
| 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, Windows PC | iOS or Android mobile device, Windows PC | iOS or Android mobile device | Same |
| Wireless Networking | IEEE 802.11 a/b/g/n | IEEE 802.11 a/b/g/n | -- | |
| 510(k) Track | Track 3 | Track 3 | Track 3 | Same |
| Compliance Standards | - AAMI/ANSI ES60601-1 (2012)<br>- IEC 60601-1-2 (2020)<br>- IEC 60601-1-6(2020)<br>- IEC 60601-1-11<br>- IEC 60601-1-12 (2014)<br>- IEC 60601-2-37 (2015)<br>- AIUM/NEMA UD 2- 2004 R2009 | - AAMI/ANSI ES60601-1 (2012)<br>- IEC 60601-1-2 (2014)<br>- IEC 60601-1-6 (2013)<br>- IEC 60601-2-37 (2008)<br>- AIUM/NEMA UD 2- 2004 R2009 | - IEC60601-1<br>- IEC 60601-1-2<br>- IEC 60601-1-6 (2013)<br>- IEC 60601-1-11<br>- IEC 60601-1-12 (2014)<br>- IEC 60601-2-37 (2015)<br>- | Same.<br>As compared to the predicate, the LU800 series comply with the |

| Item | Application device | Predicate device | Reference Device | Comparison |
|---|---|---|---|---|
| Device name | ASUS Ultrasound Imaging System (Model: LU800 series) | Leltek Ultrasound Imaging System (Model: LU700 series) | Vscan Air | - |
| | - AIUM/NEMA UD 3- 2004 R2009<br>- IEC 62133 (2012)<br>- IEC 62366 (2020)<br>- ISO 10993-1(2018)<br>- ISO 10993-5(2009)<br>- ISO 10993-10(2010)<br>- ISO 10993-23(2021)<br>- IEC 62304 (2006)<br>- ISO 15223-1 (2021)<br>- ISO 14971 (2019)<br>- ISO 13485 (2016) | - AIUM/NEMA UD 3- 2004 R2009<br>- IEC 62133 (2012)<br>- IEC 62366 (2014)<br>- ISO 10993-1(2009)<br>- ISO 10993-5(2009)<br>- ISO 10993-10(2010)<br>-<br>- IEC 62304 (2006)<br>- ISO 15223-1 (2016)<br>- ISO 14971 (2012)<br>- ISO 13485 (2016) | -<br>-<br>-<br>- ISO 10993-1<br>-<br>-<br>-<br>- ISO 62304<br>- ISO 15223-1<br>- ISO 14971<br>- | safety and performance tests, which meets all the essential requirement for its intended use. |

This device is a modification of an existing licensed device (K222365) using technologies that exist on the market as of the date of this submission. The ASUS Ultrasound Imaging System (Model: LU800 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 predicate device.

## 8. Summary of Non-Clinical Tests:

The ASUS 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 | 2020 | 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 | 2020 | Medical electrical equipment Part 1-6 General requirements for basic safety and essential performance Collateral standard Usability |
| ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] | 2015 & 2021 | Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)] |
| IEC 60601-1-12 | 2014 | Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment |
| 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 | 2006/A1:2016 | 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 10993-23 | 2021 | Biological evaluation of medical devices — Part 23: Tests for irritation |
| 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 | 2021 | 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 ASUS 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 ASUS 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 ASUS Ultrasound Imaging System, using technologies existing on the market as of the date of this submission. The ASUS Ultrasound Imaging System (Model: LU800 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 predicate device.

## 10. Conclusion

Verification and validation testing have been conducted on the ASUS Ultrasound Imaging System and ascertain that it is safe for use by qualified and trained healthcare professionals. 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 ASUS Ultrasound Imaging System are substantially equivalent in safety and effectiveness to the predicate device.