July 30, 2026

Imgfax Co., Ltd.
% Chen Salon
System engineer
Imd Medical & Drug Technology Service Institutions
Rm. 308, Bldg. 11, # 23 Jinqu Rd., Wanjiang District
Dongguan, Guangdong 523000
China

Re: K261288
Trade/Device Name: Handheld Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 31, 2026
Received: June 1, 2026

Dear Chen Salon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.30 13:24:08 -04'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261288

Please provide the device trade name(s).

Handheld Ultrasound Scanner (L12、LH20、C3、EC6、MC6、PA)

Please provide your Indications for Use below.

The Imgfax Handheld Ultrasound Scanner 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:

L12
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

LH20
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

C3
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

MC6
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)

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

EC6
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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Submitter's Identification

- Company Name: IMGFAX CO., LTD.
- Address: Unit I220, 15th Floor, Building 8, Area A, Hantian Technology City, Nanhai, Foshan, Guangdong, China
- Phone: +86 13902209560
- Contact Person (Title): shiyong.li (General Manager)
- E-mail：shiyong.li@imgfax.com

- Date of Preparation: Mar. 11, 2026

2. Name of the Device

- Trade/Proprietary Name: Handheld Ultrasound Scanner
- Model: L12、LH20、C3、EC6、MC6、PA

3. Common Name and Classification

- Device Classification Name: Ultrasonic Pulsed Doppler Imaging System
- Classification Product Code: IYN
- Subsequent Product Code: IYO, ITX
- Regulation Number: 21 CFR 892.1550
- Class:2
- Review Panel: Radiology

4. Predicate Device Information

- 510(k) Number: K241161
- Device Classification Name: Ultrasonic Pulsed Doppler Imaging System
- Sponsor: Leltek Inc.
- Classification Product Code: IYN
- Subsequent Product Code: IYO, ITX

- Regulation Number:21 CFR 892.1560
- Class:2
- Review Panel: Radiology
- Trade/Proprietary 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).

5. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail：33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

6. Device Description

The Imgfax Handheld Ultrasound Scanner 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.

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

3. 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.

4. The imaging system houses a built-in battery, multichannel beamformer, pressman converter and Wi-Fi components。

7. Indications for Use

The Imgfax Handheld Ultrasound Scanner 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:

L12

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

LH20

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

C3

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

MC6

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)

PA

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

EC6

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.

8. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	IMGFAX CO., LTD.	Leltek Inc.	/
Device Name	Handheld Ultrasound Scanner	Ultrasound Imaging System (Model: 128 series)	/
Regulation Description	Ultrasonic Pulsed Doppler Imaging System	Ultrasonic Pulsed Doppler Imaging System	SE

Review Panel	Radiology	Radiology	SE
Classification Product Code	IYN, IYO, ITX	IYN, IYO, ITX	SE
Regulation Number	21 CFR 892.1550	21 CFR 892.1550	SE
Class	Class 2	Class 2	SE
Prescription or OTC	Prescription Use	Prescription Use	SE
Environment of Use	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.	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.	SE
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	SE

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) - FAST/EFAST, - Nerve, -	SE

Table 2 Safety factor & Performance Comparison

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Software	Compliance with IEC 62304	Compliance with IEC 62304	SE
Biocompatibility	Compliance with ISO 10993-1	Compliance with ISO 10993-1	SE

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Mode of Operation	- B Mode (Ophthalmic and others) - M mode - Pulsed wave Doppler (PWD) - Color flow Doppler(CF / CD) - Power Doppler(PD) - Combined mode (B+M, B+CF, B+PWD)	- B Mode (Ophthalmic and others) - M mode - Pulsed wave Doppler (PWD) - Color flow Doppler(CF / CD) - Power Doppler(PD) - Combined mode (B+M, B+CF, B+PWD)	SE
Connect	Wireless communication via IEEE 802.11 a/b/g/n	Wireless communication via IEEE802.11 a/b/g/n	SE
Transducer Types	Linear (L12) Convex array (C3) MicroConvex array (MC6) Phased array (PA) Endocavity array (EC6) Linear (LH20)	Linear (LK128L, LK128LH LU700L,LU710L, LU710LH) Convex array (LK128C, LU700C,LU710C) MicroConvex array (LK128M, LU710M) Phased array (LK128PA, LU710PA) Endocavity array (LK128E, LU710E)	SE
Portability	Portable ultrasound system	Portable ultrasound system	SE
Power Source	Rechargeable battery (Li-ion)	Rechargeable battery (Li-ion)	SE
Display or OTC	iOS, Android mobile device or Windows	iOS, Android mobile device or Windows	SE
510(k) Track	Track 3	Track 3	SE

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Compliance Standards	- AAMI/ANSI ES60601-1 (2012) - IEC 60601-1-2 (2014) --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 --IEC62366 (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	- AAMI/ANSI ES60601-1 (2012) - IEC 60601-1-2 (2014) --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 --IEC62366 (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	SE

9. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

A series of non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards

1) Electrical safety

IEC6060-1:2005+A1:2012+A2:2020, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

ANSI AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012 + A2:2021, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

2) Electromagnetic compatibility (EMC)

IEC 60601-1-2:2014 /AMD1:2020, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests.

3) Basic Safety and Essential Performance

IEC 60601-1-6:2010+A1:2013+A2:2020, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.
IEC 62366-1 Edition 1.0 2020-06, Medical Devices - Application Of Usability Engineering To Medical Devices.

4) Software Verification and Validating Testing

Software verification and validation testing were conducted and documentation was provided as recommended by standard ISO 62304:2015 and FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

5) Biocompatibility testing

ISO 10993-5:2019 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021 Biological evaluation of medical devices - Parts 10: Tests for skin sensitization
ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation

10. Clinical Tests Performed

No clinical test data was used to support the decision of substantial equivalence.

11. Conclusion

The technological features and intended use of the subject device are included within the

scope of the predicate device. The differences do not affect the safety and effectiveness of the subject device for its intended use.

Thus, the subject device is substantially equivalent to the predicate device.