February 12, 2024

Eieling Technology Limited
% Salon Chen
System Engineer
IMD Medical & Drug Technology Service Institutions
Room 308, Building 11, No. 23 Jinqu Road, Wanjiang
District, Dongguan City
Dongguan, Guangdong 523000
CHINA

Re: K233401
Trade/Device Name: Portable Liver Elastography Ultrasound Diagnostic System (Liverscan Mobile)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: December 22, 2023
Received: January 10, 2024

Dear Salon Chen:

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.

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)*

K233401

Device Name

Portable Liver Elastography Ultrasound Diagnostic System (Liverscan Mobile)

Indications for Use *(Describe)*

The Liverscan Mobile is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter) in internal structures of the body. The shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease.

The Liverscan Mobile is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5MHz ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter).

The shear wave speed and stiffness, and MAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.

This device is designed to be used in a doctor's office to measure the stiffness and ultrasonic attenuation of the liver in patients with liver disease. It does so in a painless and completely non-invasive manner.

To ensure safe and effective operation,the operator shall meet the following requirements:

1) Receive training as required by local,state and national regulations,if applicable
2) Receive additional training as required by the authorized distributor or EIELING
3) Has a thorough knowledge and understanding of the material presented in this manual

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.

510(k) Summary

1. Submitter's Identification:

- Company Name: Eieling Technology Limited
- Address: RM 529, 5/F, Core Building 5W Hong Kong Science Park, NT Hong Kong.
- Phone: +852 6103 2309/13148822309
- Fax: +852 6103 2309
- Contact Person (Title): Lin Yangmin (General Manager)
- E-mail：alyssalin@eieling.com

- Date of Preparation: Dec. 22, 2023

2. Name of the Device:

- Portable Liver Elastography Ultrasound Diagnostic System
- Model: Liverscan Mobile

3. Common Name and Classification:

- Device Classification Name: system, imaging, pulsed echo, ultrasonic
- Classification Product Code: IYO
- Subsequent Product Code: ITX
- Regulation Number:21 CFR 892.1560
- Class:2
- Review Panel: Radiology

4. Predicate Device Information:

- 510(k) Number: K212035
- Device Classification Name: system, imaging, pulsed echo, ultrasonic
- Sponsor: Echosens
- Classification Product Code: IYO
- Subsequent Product Code: ITX

- Regulation Number:21 CFR 892.1560
- Class:2
- Review Panel: Radiology
- Trade/Proprietary Name: FibroScan® 230
- Common Name: Diagnostic Ultrasound System and Accessories

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 Liverscan Mobile is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter) in internal structures of the body. The shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease.

The Liverscan Mobile is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5MHz ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter).

The shear wave speed and stiffness, and MAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.

7. Indications for Use

The Liverscan Mobile is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter) in internal structures of the body. The shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease.

The Liverscan Mobile is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5MHz ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter).

The shear wave speed and stiffness, and MAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.

This device is designed to be used in a doctor's office to measure the stiffness and ultrasonic attenuation of the liver in patients with liver disease. It does so in a painless and completely non-invasive manner.

To ensure safe and effective operation, the operator shall meet the following requirements:

1) Receive training as required by local, state and national regulations, if applicable
2) Receive additional training as required by the authorized distributor or EIELING
3) Has a thorough knowledge and understanding of the material presented in this user manual

8. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Eieling Technology Limited	Echosens	/
Device Name	Portable Liver Elastography Ultrasound Diagnostic System	Diagnostic Ultrasound System and Accessories	/
Classification Product Code	IYO	IYO	SE
Subsequent Product Codes	ITX	ITX	SE
Regulation	21 CFR 892.1560	21 CFR 892.1560	SE
Classification Name	system, imaging, pulsed echo, ultrasonic	system, imaging, pulsed echo, ultrasonic	SE

Class	2	2	SE
Prescription or OTC	Prescription Use	Prescription Use	SE
Application	Abdominal	Abdominal	SE
Ultrasound	Piezoelectric ultrasound source	Piezoelectric ultrasound source	SE

Intended Use	The Liverscan Mobile is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter) in internal structures of the body. The shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease. The Liverscan Mobile is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5MHz ultrasound coefficient of attenuation (MAP: Mobile Attenuation Parameter). The shear wave speed and stiffness, and MAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.	The FibroScan® is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. The Shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease. The FibroScan® is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver. Shear wave speed and stiffness, and CAP may be used as an aid in the clinical management of pediatric patients with liver disease.	Note 1

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
Usability	Compliance with IEC 60601-1-6:	Compliance with IEC 60601-1-6:	SE
Usability Engineering	Compliance with IEC 62366-1	Compliance with IEC 62366-1	SE
Software	Compliance with IEC 62304	Compliance with IEC 62304	SE
Biocompatiblity	Compliance with ISO 10993-1	Compliance with ISO 10993-1	SE
Performance	Compliance with IEC 60601-2-37/ IEC 62359：2017/ IEC 61161	Compliance with IEC 60601-2-37/ IEC 62127-1/ IEC 62127-03/ IEC 61161	similar
Imaging Modes	B-mode Transient Elastography (TE)	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)	Note 2
Probes	LS01 probe (3.5 MHz)	M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) (single element ultrasound transducer)	Note 3
Depth Analysis Method	25-65 / 35-75 mm	Fixed Depth: S1 exam : 15-40 mm S2 exam : 20-50 mm Adaptive Depth (SmartDepth): M exam: 25-65 / 30-70 mm XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm	Note 4

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
VCTE™ Mode	Shear wave speed measurements and tissue stiffness	Shear wave speed measurements and tissue stiffness	SE
VCTE™ Range	Shear wave speed (0.7-5.0 m/s) Stiffness (1.5-75 kPa)	Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa)	Note 5
VCTE™ Display	Shear wave speed and stiffness medians and IQR/median ratio	Shear wave speed and stiffness medians and IQR/median ratio	SE
Attenuation Mode	Mobile Attenuation Parameter(MAP）	Controlled Attenuation Parameter (CAP)	Note 6
Attenuation Range	MAP value (100-400 dB/m)	CAP value (100-400 dB/m)	SE
Attenuation Display	MAP median and IQR	CAP mean and standard deviation	Note 7
Attenuation Display – Probes compatibility	LS01 Probe	S+ Probe M+ Probe XL Probe	Note 8
Size and Weight	525mmX175mmX315mm (Lx W x H) 4.15kg with accessories	265.5mm x 157mm x 200mm (H x W x D) 4.4kg with accessories	Note 9
Power supply	100-240 V ~ 50–60 Hz	100-240 V ~ 50–60 Hz	SE

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Core Component	Elastography engine Analog front end High frequency (US): Transducer 3.5L3213A-001 Analog front end Low frequency (servo control): Transducer 3.5L3213A-001	Elastography engine Analog front end High frequency (US): PV3 Analog front end Low frequency (servo control): PV3	Note 10
Operating system	Windows 10 Embedded	Windows 10 Embedded	SE
Screen	Size: Minimum 13 inches or above Resolution: 1920 X 1080	User's computer (Screen resolution req: 1024 x 768)	Note 11
Internet	/	An Internet connection is required prior to first usage	Note 12
Battery	Rechargeable Li-ion battery pack （Model:18650）	N/A	N/A
Accessories	N/A	N/A	N/A

As shown in the above comparison Table, Portable Liver Elastography Ultrasound Diagnostic System in similarity to the predicate device. Accordingly, we are substantially equivalent to the predicate device FibroScan® 230 (K212035).

Design and Technology – The basic design and technology of providing Portable Liver Elastography Ultrasound Diagnostic System is the same or similar.

Performance and Specifications – The subject device has similar Portable Liver Elastography Ultrasound Diagnostic System and specifications to the predicate device.

Indications – The indications include in. the predicate device scope.

Review of Differences：

Note 1:

The predicate device has 3 probes, of which S+ head is for children, M+, XL+ probe is for adult, and the proposed device' probe is for adult.

Note 2:

A mode in the predicate device is waveform signal: variable. M mode in the predicate device is the signal change of A mode in different time periods: one-dimensional graph.

The proposed device is an ultrasonic transducer with a linear array of 32 elements, and the 2D imaging is in two-dimensional mode and the B-mode is the liver ultrasonic contour morphogram (2D image).

Note 3:

The proposed device is the same as the predicate device' M+ probe, the proposed device has no S+, XL+ probe, and this difference does not affect the safety and effectiveness of the product.

Note 4:

The measurement depth of the proposed device is the same as that of the predicate device' M+ probe. Compared with the measurement depth greater than 5mm of the predicate device, it is more convenient to sample during the measurement process.

Note 5:

Stiffness scope in the proposed device is a little wider than the predicate device and the performance test report in the proposed device verifies that 1.5kPa can be measured.

Note 6:

Only terminology difference. CAP & MAP is the abbreviations of each other.

Note 7:

Only statistical parameter selection difference between the predicate device and the proposed device. IQR and standard deviation are both used to measure the degree of dispersion of data, and this difference does not affect the safety and effectiveness of the product.

Note 8:

The intended use of LS01 Probe in the proposed device is the same as M+ Probe in the predicate device.

Note 9:

Differences in weight and size between the predicate device and the proposed device do not affect safety and effectiveness of the product.

Note 10:

The predicate device is a single array ultrasonic transducer with one-dimensional imaging mode.

The proposed device is an ultrasonic transducer with a linear array of 32 elements, and the 2D imaging is in two-dimensional mode.

Note 11:

The proposed device is higher resolution than predicate device.

Note 12:

The proposed device does not connect to the Internet.

Bench 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.

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 60601-2-37: Medical Electrical Equipment - Part 2-37: Particular Requirements for The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment; Edition 2.1 2015.

   IEC 62359：2017 Ultrasonics - Field characterization - Test methods for the determination of

thermal and mechanical indices related to medical diagnostic ultrasonic field

IEC 61161: Ultrasonics -- Power Measurement -- Radiation Force Balances and Performance Requirements; Edition 3.0 2013-01.

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 2015-02: 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 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 10993-1:2009 Biological evaluation of medical devices-Parts 1: Evaluation and testing.

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

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

The proposed device is the same as the predicate device but the two devices are different. A series of safety and performance tests were conducted on the subject device:

Biocompatibility

Software Validation

Electromagnetic compatibility and electrical safety

Function test

All the test results demonstrate the Liverscan Mobile meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

10. Clinical Tests Performed

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

11. Conclusion

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate devices.