February 06, 2026

Eieling Technology (Shenzhen) Limited
℅ Chen Salon
System Engineer
IMD Medical & Drug Technology Service institutions
Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District
Dongguan, Guangdong 523000
CHINA

Re: K253221
Trade/Device Name: Liver fat ultrasound quantitative system, The FattaLab (FL-CC M1, FL-CC M1_Pro)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: January 10, 2026
Received: January 12, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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)*
K253221

Device Name
Liver fat ultrasound quantitative system The FattaLab (FL-CC M1FL-CC M1 _Pro)

Indications for Use *(Describe)*
The FattaLab provides B-mode imaging and is intended to measure ultrasound attenuation coefficient (MAP: Mobile Attenuation Parameter) of liver tissue for adult patients at 3.5MHz.
The 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 intended for use by qualified and appropriately trained healthcare professionals in hospitals, clinics or any facility where healthcare is provided to measure the ultrasound attenuation coefficient 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 the labeling

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.

K253221 **510(k) Summary**

1. Submitter's Identification:

- Company Name: Eieling Technology (Shenzhen) Limited
- Address: RM610 and RM110, Building E, Qihang Innovation Development Park, No. 1008 Songbai Road, Yangguang Community, Xili Street, Nanshan District, Shenzhen, Guangdong, P.R. China
- Phone: +86 0755-23100816/15919830132
- Fax: +852 6103 2309
- Contact Person (Title): like wang (General Manager)
- E-mail：mzzhu@eieling.com
- Date of Preparation: Jan. 11, 2026

2. Name of the Device:

- Liver fat ultrasound quantitative system、The FattaLab
- Model: FL-CC M1，FL-CC M1_Pro

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: K233401
- Device Classification Name: system, imaging, pulsed echo, ultrasonic
- Sponsor: Eieling Technology (Shenzhen) Limited

- Classification Product Code: IYO
- Subsequent Product Code: ITX
- Regulation Number:21 CFR 892.1560
- Class:2
- Review Panel: Radiology
- Trade/Proprietary Name: Liverscan Mobile
- Common Name: Portable Liver Elastography Ultrasound Diagnostic System

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 FattaLab provides B-mode imaging and is intended to provide ultrasound attenuation coefficient (MAP: Mobile Attenuation Parameter) of liver tissue for adult patients.

The FattaLab is indicated for non-invasive measurement of 3.5MHz ultrasound attenuation coefficient (MAP: Mobile Attenuation Parameter) in the liver.

The 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 FattaLab provides B-mode imaging and is intended to measure ultrasound attenuation coefficient (MAP: Mobile Attenuation Parameter) of liver tissue for adult patients at 3.5MHz.

The 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 intended for use by qualified and appropriately trained healthcare professionals in hospitals, clinics or any facility where healthcare is provided to measure the ultrasound attenuation coefficient 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 the labeling

8. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Eieling Technology（Shenzhen）Limited	Eieling Technology Limited	/
Device Name	Liver fat ultrasound quantitative system	Portable Liver Elastography Ultrasound Diagnostic System	/
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 FattaLab is intended to measure ultrasound attenuation coefficient (MAP: Mobile Attenuation Parameter) in internal structures of the body. The FattaLab is indicated for non-invasive of 3.5MHz ultrasound attenuation coefficient (MAP: Mobile Attenuation Parameter). The 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 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.	**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
Biocompatibility	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 62359：2017/ IEC 61161	SE
Imaging Modes	B-mode	B-mode Transient Elastography (TE)	**Note 3**
Probes	FL01 probe (3.5 MHz)	LS01 probe (3.5 MHz)	**Note 4**
Depth Analysis Method	25-65 / 35-75/45-85 mm	25-65 / 35-75 mm	**Note 5**
TE Mode	N/A	Shear wave speed measurements and tissue stiffness	**Note 5**

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
TE Range	N/A	Shear wave speed (0.7-5.0 m/s) Stiffness (1.5-75 kPa)	**Note 6**
TE Display	N/A	Shear wave speed and stiffness medians and IQR/median ratio	**Note 7**
Attenuation Mode	Mobile Attenuation Parameter(MAP）	Mobile Attenuation Parameter(MAP）	SE
Attenuation Range	MAP value (100-400 dB/m)	MAP value (100-400 dB/m)	SE
Attenuation Display	MAP median and IQR	MAP median and IQR	SE
Attenuation Display – Probes compatibility	FL01 Probe	LS01 Probe	**Note 8**
Size and Weight	FL-CC M1： 260mmX180mmX120mm (L x W x H) 1.5kg with accessories FL-CC M1_Pro： 310mmX230mmX170mm (L x W x H) 3kg with accessories	525mm x 175mm x 315mm (L x W x H) 4.15kg 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	(US): Transducer 3.5P3213B-302 Analog front-end Low frequency (servo control): Transducer 3.5P3213B-302	Elastography engine Analog front end High frequency (US): Transducer 3.5L3213A-001 Analog front end Low frequency (servo control): Transducer 3.5L3213A-001	**Note 10**
Operating system	Windows 10 Embedded	Windows 10 Embedded	SE
Screen	Size: Minimum 11.1 inches or above Resolution: 1920 X 1080	Size: Minimum 13 inches or above Resolution: 1920 X 1080	**Note 11**
Internet	/	/	SE
Battery	Rechargeable Li-ion battery pack （Model: YZ 103035）	Rechargeable Li-ion battery pack （Model:18650）	**Note 12**
Accessories	N/A	N/A	N/A

As shown in the above comparison Table, the subject device (Liver fat ultrasound quantitative system) does not include the transient elastography (TE) mode and liver stiffness measurement capabilities present in the predicate device (Liverscan Mobile, K233401). The subject device provides only the MAP (Mobile Attenuation Parameter) measurement function for liver fat quantification.

Design and Technology – The basic design and technology of the subject device is similar to the predicate device.

The subject device's MAP measurement function is identical to the predicate device's MAP measurement function in terms of working principle and performance indicators.

Performance and Specifications – The subject device, Liver fat ultrasound quantitative

	system, has removed the liver hardness measurement function present in the predicate device. Based on whether it is equipped with an integrated computer terminal, the device is available in two models (FL-CC M1 and FL-CC M1_Pro).

Indications – The indications are included in the predicate device scope.

Review of Differences：

Note1:

The predicate device provides 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 proposed device does not to shear wave speed measurements and estimates of tissue stiffness, only provide MAP measurement. The proposed equipment MAP measurement is intended for the same purposes as the suggested equipment, except that the proposed equipment does not have estimates of tissue stiffness measurement function.

Note2:

The proposed device does not TE mode.

Note3:

The proposed device is the same as the probe types of the predicate device; the probe models are different, but they use the same center frequency, and this difference does not affect the safety and effectiveness of the product.

Note4:

The measurement depth of the proposed device is the same as that of the predicate device's probe.

Note5:

The proposed device does not TE mode

Note6:

The proposed device does not estimate of tissue stiffness measurement function

Note7:

The proposed device does not Shear wave speed and stiffness medians and IQR/median ratio

Note8:

The measurement depth of the proposed device is the same as that of the predicate device's probe.

Note 9:

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

Note 10:

The transducers used by predicate device and proposed device are from the same manufacturer and are of the same type, but they have different models. This type of transducer 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 and the predicate device have same resolution, but the screen size is different.

Note 12:

The built-in lithium battery model is not the same, in line with IEC62133

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 as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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:

Software Validation

Electromagnetic compatibility and electrical safety

Function test

All the test results demonstrate the FattaLab 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 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.