

**K253221 Liver fat ultrasound quantitative system, The FattaLab
(FL-CC M1, FL-CC M1_Pro)**Feb 6, 2026
130 days to decisionK253221 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k253221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 29, 2025
Decision date	Feb 6, 2026
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eieling Technology (Shenzhen) Limited
Location	Shenzhen, CN
Contact	Chen Salon
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	Imd Medical & Drug Technology Service Institutions
Contact	Chen Salon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253221/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026