

**K212624 EFAI Intelligent Cardiothoracic Ratio (iCTR)  
Assessment System**Apr 4, 2022  
229 days to decisionK212624 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k212624/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 18, 2021
Decision date	Apr 4, 2022
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ever Fortune.Ai, Co., Ltd.</b>
Location	Taichung City, TW
Contact	Chen Ming-Fong
510(k) history	15 submissions · 15 cleared · 2021-2026

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212624/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026