

K242821 EFAI Chestsuite XR Malpositioned ETT Assessment System (ETT-XR-100)Feb 20, 2025
155 days to decisionK242821 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k242821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Sep 18, 2024
Decision date	Feb 20, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ever Fortune.Ai, Co., Ltd.
Location	Taichung City, TW
Contact	Chang Joseph
510(k) history	15 submissions · 15 cleared · 2021-2026

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