

K221552 EFAI ChestSuite XR Pneumothorax Assessment System

Nov 8, 2022
161 days to decision

K221552 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k221552/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	May 31, 2022
Decision date	Nov 8, 2022
Days to decision	161 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	Joseph Chang
510(k) history	15 submissions · 15 cleared · 2021-2026

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Device record: <https://www.510kdatabase.net/k221552/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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