

**K211257 EFAI PACS Picture Archiving and Communication System**Sep 10, 2021  
137 days to decisionK211257 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211257/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 26, 2021
Decision date	Sep 10, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211257/>. 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