

K232100 Efai Pacs Picture Archiving and Communication System Pro

Aug 8, 2023
25 days to decision

K232100 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k232100/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 14, 2023
Decision date	Aug 8, 2023
Days to decision	25 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k232100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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