

**K253163 EFAI ERSUITE CT APPENDICITIS ASSESSMENT  
SYSTEM (APPEN-CT-100)**Apr 22, 2026  
208 days to decisionK253163 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k253163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Sep 26, 2025
Decision date	Apr 22, 2026
Days to decision	208 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	Joseph Chang
510(k) history	15 submissions · 15 cleared · 2021-2026

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