

**K242292 uAI Easy Triage ICH**Sep 24, 2024  
53 days to decisionK242292 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k242292/>**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	Aug 2, 2024
Decision date	Sep 24, 2024
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai United Imaging Intelligence Co., Ltd.</b>
Location	Shanghai, CN
Contact	Zhao Xiaojing
510(k) history	4 submissions · 4 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra Digital Health</b>
Contact	Nima Akhlaghi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242292/> 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 13, 2026