

K251610 qER-CTA (v1.0)Sep 8, 2025
104 days to decisionK251610 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k251610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	May 27, 2025
Decision date	Sep 8, 2025
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qure.Ai Technologies
Location	Mumbai, IN
Contact	Rajesh Sukhija
510(k) history	9 submissions · 9 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251610/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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