

K250354 Viz Subdural+, Viz SUBDURAL PLUSJun 10, 2025
123 days to decisionK250354 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 7, 2025
Decision date	Jun 10, 2025
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Viz. Ai, Inc.
Location	Palo Alto, CA, US
Contact	Gregory Ramina
510(k) history	11 submissions · 10 cleared · 2018-2025

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