

K213319 Viz ANEURYSM, Viz ANXFeb 18, 2022
137 days to decisionK213319 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k213319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Oct 4, 2021
Decision date	Feb 18, 2022
Days to decision	137 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213319/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026