FDA 510(k) Premarket Notification

K213319 Viz ANEURYSM, Viz ANX

CLEARED

Feb 18, 2022
137 days to decision

K213319 · 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