FDA 510(k) Premarket Notification

K220439 Viz SDH

CLEARED

Jul 25, 2022
159 days to decision

K220439 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k220439/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Feb 16, 2022
Decision date	Jul 25, 2022
Days to decision	159 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	Vi Ma
510(k) history	11 submissions · 10 cleared · 2018-2025