

K190424 HealthICHJun 13, 2019
111 days to decisionK190424 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k190424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Feb 22, 2019
Decision date	Jun 13, 2019
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zebra Medical Vision, Ltd.
Location	Sefayim, IL
Contact	Flair Bar
510(k) history	9 submissions · 9 cleared · 2018-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190424/> 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