

K190362 HealthPNXMay 6, 2019
80 days to decisionK190362 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k190362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Feb 15, 2019
Decision date	May 6, 2019
Days to decision	80 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

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