

**K192320 HealthCXR**Nov 26, 2019  
92 days to decisionK192320 · Product code: **QFM** · Radiology  
Source: <https://www.510kdatabase.net/k192320/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Aug 26, 2019
Decision date	Nov 26, 2019
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192320/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026