

K200905 HealthMammoJul 16, 2020
101 days to decisionK200905 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k200905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Apr 6, 2020
Decision date	Jul 16, 2020
Days to decision	101 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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