FDA 510(k) Premarket Notification

K211803 HealthPPT

CLEARED

Dec 15, 2021
187 days to decision

K211803 · Product code: **QFM** · Radiology
Source: https://www.510kdatabase.net/k211803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Jun 11, 2021
Decision date	Dec 15, 2021
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211803/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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