

K231871 Radify TriageJan 17, 2024
205 days to decisionK231871 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k231871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Jun 26, 2023
Decision date	Jan 17, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Envisionit Deepai, Ltd.
Location	Cobham, GB
Contact	Jaishree Naidoo
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Hardian Ltd T/A Hardian Health
Contact	Michael Pogose

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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