

K223754 BraveCXNov 9, 2023
329 days to decisionK223754 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k223754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Dec 15, 2022
Decision date	Nov 9, 2023
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bering, Ltd.
Location	London, GB
Contact	Drozдов Ignat
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Dawa Medical, LLC
Contact	Stephan Toupin

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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