

K203517 Saige-QApr 16, 2021
137 days to decisionK203517 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k203517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Nov 30, 2020
Decision date	Apr 16, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DeepHealth, Inc.
Location	Cambridge, MA, US
Contact	A. Gregory Sorensen
510(k) history	8 submissions · 8 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203517/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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