

K253825 Saige-DxJun 15, 2026
196 days to decisionK253825 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k253825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Dec 1, 2025
Decision date	Jun 15, 2026
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DeepHealth, Inc.
Location	Cambridge, MA, US
Contact	B. Nathan Hunt
510(k) history	10 submissions · 10 cleared · 2021-2026

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