

**K241747 Saige-Dx**

Nov 18, 2024  
153 days to decision

K241747 · Product code: **QDQ** · Radiology  
Source: <https://www.510kdatabase.net/k241747/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jun 18, 2024
Decision date	Nov 18, 2024
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DeepHealth, Inc.</b>
Location	Cambridge, MA, US
Contact	B. Nathan Hunt
510(k) history	8 submissions · 8 cleared · 2021-2025

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