

K251873 Saige-Dx

Aug 11, 2025
54 days to decision

K251873 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k251873/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jun 18, 2025
Decision date	Aug 11, 2025
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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