

**K243688 Saige-Dx (3.1.0)**

Dec 19, 2024  
20 days to decision

K243688 · Product code: **QDQ** · Radiology  
Source: <https://www.510kdatabase.net/k243688/>

**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	Nov 29, 2024
Decision date	Dec 19, 2024
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---