

K222275 Saige-DensityDec 16, 2022
140 days to decisionK222275 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k222275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 29, 2022
Decision date	Dec 16, 2022
Days to decision	140 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

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