

K254131 BACMay 21, 2026
150 days to decisionK254131 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k254131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 22, 2025
Decision date	May 21, 2026
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	DeepHealth, Inc.
Location	Cambridge, MA, US
Contact	B. Nathan Hunt
510(k) history	9 submissions · 9 cleared · 2021-2026

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