

K251527 Brain WMHSep 25, 2025
129 days to decisionK251527 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 19, 2025
Decision date	Sep 25, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quantib B.V.
Location	Rotterdam, NL
Contact	Nathan Hunt
510(k) history	11 submissions · 11 cleared · 2016-2026

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