

K240680 CDM InsightsDec 6, 2024
270 days to decisionK240680 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k240680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 11, 2024
Decision date	Dec 6, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oxford Brain Diagnostics, Ltd.
Location	Oxford, GB
Contact	Terry Pollard
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Ken Blocking Consulting, LLC
Contact	Yulia Nikova

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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