

K250369 Axial3D InsightSep 18, 2025
220 days to decisionK250369 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 10, 2025
Decision date	Sep 18, 2025
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Axial Medical Printing Limited
Location	Belfast, GB
Contact	Flatley Joanne
510(k) history	5 submissions · 5 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	CS Life Sciences, Ltd.
Contact	May Lee

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

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