

K232841 Axial3D InsightNov 15, 2023
62 days to decisionK232841 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k232841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 14, 2023
Decision date	Nov 15, 2023
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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