

**K222745 Axial3D Insight**Jul 3, 2023  
294 days to decisionK222745 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k222745/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received         | Sep 12, 2022   |
| Decision date         | Jul 3, 2023  |
| Days to decision      | 294 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Axial Medical Printing Limited</b> |
| Location       | Belfast, GB                           |
| Contact        | Jenna McGarry                         |
| 510(k) history | 5 submissions · 5 cleared · 2022-2025 |

**REGULATORY CONSULTANT**

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|-----------------|---------------------------|
| Consulting firm | <b>Maxis Medical, LLC</b> |
| Contact         | Sujith Shetty             |

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222745/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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