

K221511 Axial3D Cloud Segmentation ServiceJun 23, 2022
30 days to decisionK221511 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k221511/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | May 24, 2022 |
| Decision date | Jun 23, 2022 |
| Days to decision | 30 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Prithul Bom |

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

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