

**K231607 Axial3D Cloud Segmentation Service**Jan 24, 2024  
237 days to decisionK231607 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k231607/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 1, 2023
Decision date	Jan 24, 2024
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231607/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026