

**K150069 Fine Structure Analysis(fineSA)**May 22, 2015  
129 days to decisionK150069 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k150069/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 13, 2015
Decision date	May 22, 2015
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Acuitas Medical , Ltd.</b>
Location	Swansea, GB
Contact	John Heinrich
510(k) history	1 submissions · 1 cleared · 2015-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150069/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026