

**K222987 Akunah REFLECT**May 10, 2023  
224 days to decisionK222987 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k222987/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 28, 2022
Decision date	May 10, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Akunah Pty, Ltd.</b>
Location	Brisbane, AU
Contact	Shanthan Pather
510(k) history	1 submissions · 1 cleared · 2023-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222987/> 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 27, 2026