

K253784 3DICOM MD CloudJan 8, 2026
43 days to decisionK253784 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k253784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 26, 2025
Decision date	Jan 8, 2026
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Singular Health Pty, Ltd.
Location	Subiaco, AU
Contact	Andre Marchezini Rocha
510(k) history	2 submissions · 2 cleared · 2022-2026

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