

K222470 3Dicom MDOct 25, 2022
70 days to decisionK222470 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k222470/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 16, 2022
Decision date	Oct 25, 2022
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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