

K221463 ElucidVivo A.3Jun 17, 2022
29 days to decisionK221463 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k221463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 19, 2022
Decision date	Jun 17, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elucid Bioimaging, Inc.
Location	Wenham, MA, US
Contact	Doug Shufelt
510(k) history	4 submissions · 4 cleared · 2017-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221463/> 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 26, 2026