

K243069 LUMYS (V1)May 2, 2025
217 days to decisionK243069 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k243069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 27, 2024
Decision date	May 2, 2025
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intradys
Location	Brest, FR
Contact	Tiffany VAZ
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243069/> 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 14, 2026