

K230044 Pre-SureMay 26, 2023
140 days to decisionK230044 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k230044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 6, 2023
Decision date	May 26, 2023
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lazarus 3D
Location	Albany, OR, US
Contact	Smriti Zaneveld
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Obelix Consulting
Contact	Elisa Maldonado-Holmertz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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