FDA 510(k) Premarket Notification

K230044 Pre-Sure

CLEARED

May 26, 2023
140 days to decision

K230044 · 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