FDA 510(k) Premarket Notification

K201835 PRE-SURE

CLEARED

Jul 8, 2021
371 days to decision

K201835 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k201835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 2, 2020
Decision date	Jul 8, 2021
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lazarus 3D, Inc.**
Location	Corvallis, OR, US
Contact	Smriti Zanevald
510(k) history	1 submissions · 1 cleared · 2021-2021

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