

**K201835 PRE-SURE**Jul 8, 2021  
371 days to decisionK201835 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k201835/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Obelix Consulting</b>
Contact	Elisa Maldonado-Holmertz

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201835/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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