

**K193172 Luna XD Ti Interbody Fusion System**Jul 2, 2020  
230 days to decisionK193172 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k193172/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 15, 2019
Decision date	Jul 2, 2020
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Benvenue Medical, Inc.</b>
Location	Mountain View, CA, US
Contact	Laurent Schaller
510(k) history	8 submissions · 8 cleared · 2007-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Justin Eggleton

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/k193172/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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