

**K162431 Luna 3D Interbody Fusion System**Nov 17, 2016  
78 days to decisionK162431 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k162431/>**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	Aug 31, 2016
Decision date	Nov 17, 2016
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162431/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026