

**K212389 Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF**Oct 29, 2021  
88 days to decisionK212389 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k212389/>**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 2, 2021
Decision date	Oct 29, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intelivation, LLC</b>
Location	Saint Simons Island, GA, US
Contact	Amit Sinha
510(k) history	2 submissions · 2 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQMIS, Inc.</b>
Contact	Barry Sands

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212389/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026