

**K201287 Impulse Interbody Fusion System**Dec 22, 2020  
222 days to decisionK201287 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k201287/>**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	May 14, 2020
Decision date	Dec 22, 2020
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Degen Medical</b>
Location	Florence, SC, US
Contact	Craig Black
510(k) history	16 submissions · 16 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201287/> 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 May 25, 2026