

**K193457 AUDERE Lumbar Spacer System**May 12, 2020  
148 days to decisionK193457 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k193457/>**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	Dec 16, 2019
Decision date	May 12, 2020
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Met One Technologies</b>
Location	El Paso, TX, US
Contact	Kyle Atwood
510(k) history	3 submissions · 3 cleared · 2017-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193457/> 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