

**K200316 UNiD IB3D ALIF**Oct 30, 2020  
266 days to decisionK200316 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k200316/>**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	Feb 7, 2020
Decision date	Oct 30, 2020
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International SA</b>
Location	Neyron, FR
Contact	David Ryan
510(k) history	25 submissions · 25 cleared · 2015-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200316/> 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 14, 2026