

**K181963 ostaPek Interbody Fusion Cages**Nov 14, 2018  
114 days to decisionK181963 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k181963/>**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	Jul 23, 2018
Decision date	Nov 14, 2018
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coligne AG</b>
Location	Zurich, CH
Contact	Robert Lange
510(k) history	4 submissions · 4 cleared · 2017-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181963/> 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 27, 2026