

**K100544 IMPIX LUMBAR INTERBODY DEVICE**Jul 22, 2010  
147 days to decisionK100544 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k100544/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 25, 2010
Decision date	Jul 22, 2010
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea Technologies</b>
Location	Round Rock, TX, US
Contact	JD WEBB
510(k) history	14 submissions · 14 cleared · 2007-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100544/> 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 18, 2026