

**K143297 Ardis Interbody System, BAK Interbody Fusion System, BAK/C Anterior Cervical Interbody Fusion System, InFix Anterior Lumbar System, TraXis Vertebral Body Replacement (Ti and VUE)**Feb 12, 2015  
87 days to decisionK143297 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k143297/>**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	Nov 17, 2014
Decision date	Feb 12, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer Spine, Inc.</b>
Location	Minneapolis, MN, US
Contact	Donna M. Semlak
510(k) history	38 submissions · 35 cleared · 2004-2016

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