

K131242 ARDIS INTERBODY SYSTEMSep 3, 2013
125 days to decisionK131242 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k131242/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 1, 2013
Decision date	Sep 3, 2013
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer Spine, Inc.
Location	Minneapolis, MN, US
Contact	JON GILBERT
510(k) history	38 submissions · 35 cleared · 2004-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131242/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026