

K133947 IRIX-A LUMBAR INTEGRATED FUSION SYSTEMJul 29, 2014
218 days to decisionK133947 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k133947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 23, 2013
Decision date	Jul 29, 2014
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	X-Spine Systems, Inc.
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN
510(k) history	34 submissions · 34 cleared · 2005-2018

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