

K171567 IRIX-A Lumbar Integrated Fusion SystemAug 28, 2017
90 days to decisionK171567 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k171567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	May 30, 2017
Decision date	Aug 28, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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