

K162944 Irix-C Cervical Integrated Fusion SystemNov 7, 2016
17 days to decisionK162944 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k162944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 21, 2016
Decision date	Nov 7, 2016
Days to decision	17 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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