

**K160428 Certex Spinal Fixation System**May 5, 2016  
79 days to decisionK160428 · Product code: **NKG** · Orthopedic  
Source: <https://www.510kdatabase.net/k160428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Feb 16, 2016
Decision date	May 5, 2016
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X-Spine Systems, Inc.</b>
Location	Centerville, OH, US
Contact	David Kirschman
510(k) history	34 submissions · 34 cleared · 2005-2018

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