

**K131615 POLARIS SPINAL SYSTEM**Sep 4, 2013  
93 days to decisionK131615 · Product code: **OSH** · Orthopedic  
Source: <https://www.510kdatabase.net/k131615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)
Date received	Jun 3, 2013
Decision date	Sep 4, 2013
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet Spine (Aka Ebi, LLC)</b>
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY
510(k) history	13 submissions · 13 cleared · 2010-2014

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