

**K150321 EVOS Lumbar Interbody System**Jul 13, 2015  
154 days to decisionK150321 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k150321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 9, 2015
Decision date	Jul 13, 2015
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cutting Edge Spine, LLC</b>
Location	Waxhaw, NC, US
Contact	John Souza
Website	<a href="https://cuttingedgespine.com">https://cuttingedgespine.com</a>
510(k) history	11 submissions · 11 cleared · 2011-2025

Cutting Edge Spine, LLC develops and commercializes spinal implant systems with a focus on bioactive materials and trabecular fixation technologies. Headquartered in North Carolina, the company was founded in 2009 and operates with a manufacturing facility in Waxhaw, US. The company has received FDA 510(k) clearances from total submissions since 2011. All submissions focus on Orthopedic devices, including cervical and lumbar interbody fusion systems and sacroiliac joint fixation platforms. The latest clearance in 2025 confirms the company remains active in device developm...

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