

**K230689 T-FIX™ 3DSI Joint Fusion System**Apr 5, 2023  
23 days to decisionK230689 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k230689/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Mar 13, 2023
Decision date	Apr 5, 2023
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cutting Edge Spine, LLC</b>
Location	Waxhaw, NC, US
Contact	Kyle Kuntz
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...