

K190025 EVOL® -SI Joint Fusion SystemAug 12, 2019
217 days to decisionK190025 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k190025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jan 7, 2019
Decision date	Aug 12, 2019
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cutting Edge Spine, LLC
Location	Waxhaw, NC, US
Contact	Kyle Kuntz
Website	https://cuttingedgespine.com
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...
