

K250605 EVOL® ha – Hyper C Cervical Interbody Fusion SystemMar 12, 2025
12 days to decisionK250605 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k250605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 28, 2025
Decision date	Mar 12, 2025
Days to decision	12 days
Third-party review	No
Combination product	No
PCCP authorized	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...