FDA 510(k) Premarket Notification

CLEARED

K214123 T-FIX® 3DSI Joint Fusion System

Jun 24, 2022
176 days to decision

K214123 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k214123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 30, 2021
Decision date	Jun 24, 2022
Days to decision	176 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k214123/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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