FDA 510(k) Premarket Notification

# K102957 CUTTING EDGE SPINE INTERBODY FUSION DEVICE

**CLEARED**

Apr 28, 2011
205 days to decision

K102957 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k102957/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Oct 5, 2010 |
| Decision date | Apr 28, 2011 |
| Days to decision | 205 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Cutting Edge Spine, LLC** |
| Location | Waxhaw, NC, US |
| Contact | JOHN KAPITAN |
| 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...