

K243074 Spectrum Spine Lumbar Cage SystemApr 4, 2025
189 days to decisionK243074 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k243074/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Sep 27, 2024 |
| Decision date | Apr 4, 2025 |
| Days to decision | 189 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Spectrum Spine, Inc. |
| Location | Jasper, GA, US |
| Contact | Scott Baltsen |
| Website | https://spectrumspine.com |
| 510(k) history | 3 submissions · 3 cleared · 2024-2025 |

Spectrum Spine, Inc. develops spinal implant systems for orthopedic surgery. The company operates with a manufacturing facility in Jasper, US, and focuses on innovative solutions for spinal fusion procedures. The company has received FDA 510(k) clearances from total submissions. All submissions fall within the Orthopedic device category. Spectrum Spine achieved its first clearance in 2024 and most recently in 2025, demonstrating active regulatory engagement. Recent cleared devices include expandable titanium systems for posterior lumbar interbody fusion, as well as lumbar...

REGULATORY CONSULTANT

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|-----------------|------------------------|
| Consulting firm | MRC Global, LLC |
| Contact | Christine Scifert |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
