

**K210044 Crystal Spinal System & Vertu Spinal System, Lucent Spinal System, Zeus Spinal System, Ceres-C Spinal System, Omega XP Spinal System**Jun 30, 2021  
174 days to decisionK210044 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k210044/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 7, 2021
Decision date	Jun 30, 2021
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spinal Elements, Inc.</b>
Location	Carlsbad, CA, US
Contact	Julie Lamothe
Website	<a href="https://www.spinalelements.com">https://www.spinalelements.com</a>
510(k) history	48 submissions · 48 cleared · 2007-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210044/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026