

**K133126 K7 LUMBAR SPACERS**Dec 9, 2013  
70 days to decisionK133126 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k133126/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 30, 2013
Decision date	Dec 9, 2013
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>K7, LLC</b>
Location	Chesterland, OH, US
Contact	KAREN E WARDEN, PHD
510(k) history	3 submissions · 3 cleared · 2013-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133126/> 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 17, 2026