

**K123388 K7C SPACER**Jan 4, 2013  
63 days to decisionK123388 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k123388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 2, 2012
Decision date	Jan 4, 2013
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123388/> 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