

**K131449 COALITION SPACER**Jul 30, 2013  
71 days to decisionK131449 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k131449/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 20, 2013
Decision date	Jul 30, 2013
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Globus Medical, Inc.</b>
Location	Audubon, PA, US
Contact	CHRISTINA KICHULA
Website	<a href="https://www.globusmedical.com">https://www.globusmedical.com</a>
510(k) history	171 submissions · 168 cleared · 2003-2026

Globus Medical, Inc. is a publicly traded orthopedic medical device company headquartered in Audubon, Pennsylvania. The company designs, develops, and commercializes products enabling surgeons to promote healing in patients with musculoskeletal disorders. Globus Medical has received FDA 510(k) clearances from total submissions since its first clearance in 2003. The company's regulatory portfolio is dominated by orthopedic devices, representing 98% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued innovation and market presenc...

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