

**K192115 SABLE Expandable Spacer**Jan 14, 2020  
161 days to decisionK192115 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k192115/>**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	Aug 6, 2019
Decision date	Jan 14, 2020
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Globus Medical, Inc.</b>
Location	Audubon, PA, US
Contact	Kelly J. Baker
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...