

**K143578 SUSTAIN R TPS Spacers, PATRIOT TPS Spacers, CALIBER TPS Spacer, COALITION TPS Spacers, INDEPENDENCE TPS Spacer, FORTIFY -R TPS Corpectomy Spacer, FORTIFY I-R TPS Corpectomy Spacer, XPand -R TPS Corpectomy Spacer, NIKO TPS Corpectomy Spacer**

Apr 13, 2016  
483 days to decision

K143578 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k143578/>

**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	Dec 17, 2014
Decision date	Apr 13, 2016
Days to decision	483 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...