

K172269 FORTRESS™ Radiopaque Bone Cement (FORTRESS™ and FORTRESS-Plus™), CREO® Fenestrated Screw System, REVLOK® Fenestrated Screw SystemMar 27, 2018
242 days to decisionK172269 · Product code: PML · Orthopedic
Source: <https://www.510kdatabase.net/k172269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Jul 28, 2017
Decision date	Mar 27, 2018
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Globus Medical, Inc.
Location	Audubon, PA, US
Contact	Kelly J. Baker
Website	https://www.globusmedical.com
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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