FDA 510(k) Premarket Notification

K180817 AERIAL™ Interspinous Fixation

CLEARED

May 21, 2018
53 days to decision

K180817 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k180817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Mar 29, 2018
Decision date	May 21, 2018
Days to decision	53 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...