FDA 510(k) Premarket Notification

K093294 REVERE STABILIZATION SYSTEM

CLEARED

Feb 17, 2010
119 days to decision

K093294 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k093294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 21, 2009
Decision date	Feb 17, 2010
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Globus Medical, Inc.**
Location	Audubon, PA, US
Contact	KELLY J BAKER, PH.D
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...