FDA 510(k) Premarket Notification

K081906 PROTEX CT CERVICOTHORACIC SPINAL SYSTEM

CLEARED

Nov 14, 2008
134 days to decision

K081906 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k081906/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jul 3, 2008
Decision date	Nov 14, 2008
Days to decision	134 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081906/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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