CLEARED

Nov 6, 2018
118 days to decision

K181846 ASSURE Anterior Cervical Plate System, PROVIDENCE Anterior Cervical Plate System, VIP Anterior Cervical Plate System, XTEND Anterior Cervical Plate System, UNIFY Dynamic Anterior Cervical Plate System, CITADEL Anterior Lumbar Plate System, TRUSS Thoracolumbar Plate System, PLYMOUTH Thoracolumbar Plate System, SP-Fix Spinous Process Fixation Plate, RELIEVE Laminoplasty Fixation System

K181846 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k181846/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jul 11, 2018
Decision date	Nov 6, 2018
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Globus Medical, Inc.**
Location	Audubon, PA, US
Contact	Lori Burns
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...