FDA 510(k) Premarket Notification

K234035 COSINE™ Spacer

CLEARED

Sep 6, 2024
261 days to decision

K234035 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k234035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 20, 2023
Decision date	Sep 6, 2024
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Globus Medical, Inc.**
Location	Audubon, PA, US
Contact	Jennifer Antonacci
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...