FDA 510(k) Premarket Notification

CLEARED

K240568 DuraPro™ Oscillating System

Apr 29, 2024
60 days to decision

K240568 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k240568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 29, 2024
Decision date	Apr 29, 2024
Days to decision	60 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...