FDA 510(k) Premarket Notification

K033115 ORTHODEK

CLEARED

Nov 17, 2003
48 days to decision

K033115 · Product code: **GAM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k033115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Sep 30, 2003
Decision date	Nov 17, 2003
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Teleflex Medical**
Location	Fall River, MA, US
Contact	STEPHEN PAGE
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...