FDA 510(k) Premarket Notification

K033654 FORCE FIBER

CLEARED

Jan 15, 2004
55 days to decision

K033654 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k033654/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Nov 21, 2003
Decision date	Jan 15, 2004
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Teleflex Medical**
Location	Fall River, MA, US
Contact	LYNN MATOS
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...