FDA 510(k) Premarket Notification

K041216 SMITH & NEPHEW ULTRABRAID SUTURE

CLEARED

Jun 7, 2004
28 days to decision

K041216 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k041216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	May 10, 2004
Decision date	Jun 7, 2004
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	DENISE LIMA
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...