FDA 510(k) Premarket Notification

K885143 ABSORBENT GAUZE ROLL

CLEARED

Feb 10, 1989
57 days to decision

K885143 · Product code: **EFQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k885143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	Dec 15, 1988
Decision date	Feb 10, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	JOHN LUSTIG
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...