FDA 510(k) Premarket Notification

CLEARED

K864264 TRICOTEX WOUND CONTACT LAYER DRESSING

Dec 29, 1986
61 days to decision

K864264 · Product code: **NAB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k864264/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Gauze / Sponge,nonresorbable For External Use (NAB)
Date received	Oct 29, 1986
Decision date	Dec 29, 1986
Days to decision	61 days
Third-party review	No

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	HOMER GREGORY
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k864264/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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