

K872988 TRANSIGEN EXUDATE CONTROLLED WOUND DRESSING

Sep 16, 1987
47 days to decisionK872988 · Product code: **NAD** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k872988/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Dressing, Wound, Occlusive (NAD)
Date received	Jul 31, 1987
Decision date	Sep 16, 1987
Days to decision	47 days
Third-party review	No

APPLICANT

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

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