FDA 510(k) Premarket Notification

# K885142 GAUZE SWABS, NON-STERILE

**CLEARED**

Jan 24, 1989
40 days to decision

K885142 · Product code: **EFQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k885142/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gauze/sponge, Internal (EFQ) |
| Date received | Dec 15, 1988 |
| Decision date | Jan 24, 1989 |
| Days to decision | 40 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...

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k885142/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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