

K100787 RENASYS F/-AB ABDOMINAL WOUND DRESSING KITSep 17, 2010
182 days to decisionK100787 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Mar 19, 2010
Decision date	Sep 17, 2010
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	LAURA D REYNOLDS
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...
