

**K082211 RENASYS-F NEGATIVE PRESSURE WOUND
THERAPY FOAM DRESSING KITS**Nov 14, 2008
100 days to decisionK082211 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k082211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Aug 6, 2008
Decision date	Nov 14, 2008
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	McHenry, IL, US
Contact	LAURA KREJCI
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...