

**K110647 RENASYS FOAM NPWT WOUND DRESSING KITS WITH SUCTION PAD**Jun 22, 2011  
107 days to decisionK110647 · Product code: **OMP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k110647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Mar 7, 2011
Decision date	Jun 22, 2011
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary
Other names	RENASYS GAUZE NPWT WOUND DRESSING KITS WITH SUCTION PAD; RENASYS

**APPLICANT**

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Company	<b>Smith &amp; Nephew, Inc.</b>
Location	Mchenry, IL, US
Contact	LAURA REYNOLDS
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
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...