

**K162129 RENASYS-G Gauze Dressing Kits with Soft Port**Aug 31, 2016  
30 days to decisionK162129 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162129/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Aug 1, 2016
Decision date	Aug 31, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**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...

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