

**K142979 RENASYS**Apr 29, 2015  
196 days to decisionK142979 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142979/>**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	Oct 15, 2014
Decision date	Apr 29, 2015
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary
Other names	EZ MAX Negative Pressure Wound Therapy; Foam NPWT Wound Dressing Kits with Soft Port; Gauze NPWT Wound Dressing Kits with Soft Port; EZ PLUS/EZ MAX Canisters

**APPLICANT**

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Company	<b>Smith &amp; Nephew, Inc.</b>
Location	McHenry, IL, US
Contact	Laurea 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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