

**K151326 RENASYS<sub>2</sub> EZ PLUS Negative Pressure Wound Therapy Device**Jul 16, 2015  
59 days to decisionK151326 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k151326/>**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	May 18, 2015
Decision date	Jul 16, 2015
Days to decision	59 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k151326/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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