

**K153209 RENASYS TOUCH Negative Pressure Wound Therapy, RENASYS TOUCH Canisters, RENASYS TOUCH Carry Bag, Carry Strap, RENASYS Y-Connector, RENASYS TOUCH IV Pole/Bed Clamp, RENASYS TOUCH Class 2 Power Supply**Aug 4, 2016  
273 days to decisionK153209 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153209/>**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	Nov 5, 2015
Decision date	Aug 4, 2016
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smith &amp; Nephew Medical, Ltd.</b>
Location	Hull, GB
Contact	LAURA REYNOLDS
510(k) history	7 submissions · 7 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153209/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026