

**K181822 RENASYS Touch**Mar 21, 2019  
255 days to decisionK181822 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181822/>**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	Jul 9, 2018
Decision date	Mar 21, 2019
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RENASYS Y-Connector

**APPLICANT**

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Company	<b>Smith &amp; Nephew Medical Limited</b>
Location	Hull, GB
Contact	Lavinia Tompkins
510(k) history	20 submissions · 20 cleared · 2016-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Smith and Nephew</b>
Contact	Kulsum Master

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181822/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026