

**K213853 RENASYS™-WF White Foam NPWT Dressing Small**Feb 10, 2023  
427 days to decisionK213853 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213853/>**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	Dec 10, 2021
Decision date	Feb 10, 2023
Days to decision	427 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RENASYS™-WF White Foam NPWT Dressing Large

**APPLICANT**

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Company	<b>Smith and Nephew Medical Limited</b>
Location	Hull, GB
Contact	Jean-Marie Steeve
510(k) history	2 submissions · 2 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213853/> 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 May 26, 2026