

**K202783 Renasys-F XL Foam Dressing Kit With Soft Port,  
Renasys XL Transparent Film Dressing**Jan 14, 2022  
479 days to decisionK202783 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202783/>**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	Sep 22, 2020
Decision date	Jan 14, 2022
Days to decision	479 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202783/> 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 13, 2026