

**K161935 Avance Foam Dressing Kit - XL**Nov 4, 2016  
113 days to decisionK161935 · Product code: **OMP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k161935/>**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 14, 2016
Decision date	Nov 4, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Molnlycke Health Care Us, LLC</b>
Location	Norcross, GA, US
Contact	MEGAN BEVILL
510(k) history	27 submissions · 27 cleared · 2006-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161935/> 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 June 2, 2026