

**K100029 MEPILEX BORDER AG DRESSING**Sep 15, 2010  
252 days to decisionK100029 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100029/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jan 6, 2010
Decision date	Sep 15, 2010
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Molnlycke Health Care</b>
Location	Newton, PA, US
Contact	STEVEN DOWDLEY
Website	<a href="http://www.molnlycke.com/">http://www.molnlycke.com/</a>
510(k) history	9 submissions · 9 cleared · 2003-2014

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100029/> Data sourced from FDA 510(k) public records (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 7, 2026