

**K102923 BARRIER N95 PARTICULATE RESPIRATOR**Nov 19, 2010  
49 days to decisionK102923 · Product code: **MSH** · General Hospital  
Source: <https://www.510kdatabase.net/k102923/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Respirator, Surgical (MSH)
Date received	Oct 1, 2010
Decision date	Nov 19, 2010
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Molnlycke Health Care</b>
Location	Newton, PA, US
Contact	CAITLIN SENTER
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/k102923/> 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 7, 2026