

**K965107 MEDLINE ADMISSION KITS**Mar 11, 1997  
81 days to decisionK965107 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k965107/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 20, 1996
Decision date	Mar 11, 1997
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medline Industries, Inc.</b>
Location	Mchenry, IL, US
Contact	CHRISTINE GALEA
510(k) history	238 submissions · 234 cleared · 1977-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965107/> 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 28, 2026