

**K214108 Medline Orbis Chemo Surgical Gown**May 6, 2022  
128 days to decisionK214108 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k214108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 29, 2021
Decision date	May 6, 2022
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medline Industries, LP</b>
Location	Nortfield, IL, US
Contact	Adam Ostrower
Website	<a href="https://www.medline.com">https://www.medline.com</a>
510(k) history	29 submissions · 29 cleared · 2022-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214108/> 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