

**K202447 Medline Orbis Surgical Gown**Apr 2, 2021  
219 days to decisionK202447 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k202447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 26, 2020
Decision date	Apr 2, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medline Industries, Inc.</b>
Location	Mchenry, IL, US
Contact	Adam Ostrower
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/k202447/> 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 May 14, 2026