

**K172954 Medline Prevention CoolZone Gown**Jun 15, 2018  
262 days to decisionK172954 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k172954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 26, 2017
Decision date	Jun 15, 2018
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medline Industries, Inc.</b>
Location	Mchenry, IL, US
Contact	Pauline Maralit
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/k172954/> 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 30, 2026