

**K160339 Cardinal Health Isolation Gown**Jul 28, 2016  
171 days to decisionK160339 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k160339/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Feb 8, 2016
Decision date	Jul 28, 2016
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardinal Health200, LLC</b>
Location	Waukegan, IL, US
Contact	Caroline Miceli
510(k) history	26 submissions · 26 cleared · 2011-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160339/> 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 2, 2026