

**K182830 Cardinal Health™ Poly-Coated Open-Back Protective Gown**

Apr 26, 2019  
203 days to decision

K182830 · Product code: **QPC** · General Hospital  
Source: <https://www.510kdatabase.net/k182830/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Non-sterile, Non-isolation, Intended To Provide Moderate Or High Barrier Protection (QPC)
Date received	Oct 5, 2018
Decision date	Apr 26, 2019
Days to decision	203 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/k182830/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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