

**K193327 Cardinal Health ChemoPlus Full Coverage Gown,  
Closed Back, Cardinal Health ChemoPlus Full Coverage Gown,  
Open Back, Cardinal Health ChemoPlus Full Coverage Sleeve**

Mar 20, 2020  
109 days to decision

K193327 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k193327/>

**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gown, Surgical (FYA)               |
| Date received         | Dec 2, 2019                        |
| Decision date         | Mar 20, 2020                       |
| Days to decision      | 109 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/k193327/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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