

# K153316 Cardinal Health Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow)

May 12, 2016  
177 days to decision

K153316 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k153316/>

## SUBMISSION DETAILS

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Surgeon&apos;s Gloves (KGO)        |
| Date received         | Nov 17, 2015                       |
| Decision date         | May 12, 2016                       |
| Days to decision      | 177 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

## APPLICANT

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|                |   |
|----------------|---|
| Company        | <b>Cardinal Health, Inc.</b>  |
| Location       | Waukegan, IL, US  |
| Contact        | Megan Middaugh  |
| Website        | <a href="http://www.cardinalhealth.com">http://www.cardinalhealth.com</a> |
| 510(k) history | 26 submissions · 26 cleared · 2006-2017                                   |

Cardinal Health, Inc. is an American multinational health care services company headquartered in Dublin, Ohio. The company specializes in pharmaceutical distribution and medical product manufacturing, serving over 100,000 locations across the United States. Cardinal Health has received FDA 510(k) clearances from total submissions between 2006 and 2017. The company&apos;s regulatory focus centers on surgical gloves and protective apparel, including sterile and powder-free formulations. This historical record reflects the company&apos;s established presence in General Hospital device...