

K160411 Cardinal Health Vinyl Powder-Free Exam Gloves with Neu-thera CoatingJul 25, 2016
160 days to decisionK160411 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k160411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Feb 16, 2016
Decision date	Jul 25, 2016
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardinal Health, Inc.
Location	Waukegan, IL, US
Contact	Megan Middaugh
Website	http://www.cardinalhealth.com
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's regulatory focus centers on surgical gloves and protective apparel, including sterile and powder-free formulations. This historical record reflects the company's established presence in General Hospital device...

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Device record: <https://www.510kdatabase.net/k160411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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