

K160875 Cardinal Health Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel CoatingJul 11, 2016
103 days to decisionK160875 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k160875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Mar 30, 2016
Decision date	Jul 11, 2016
Days to decision	103 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/k160875/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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