

K170198 Cardinal Health Sterile Polyisoprene Blend Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White)

Jun 15, 2017
143 days to decision

K170198 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k170198/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jan 23, 2017
Decision date	Jun 15, 2017
Days to decision	143 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...