

K111878 PROTEXIS LATEX BLUE WITH NEU-THERA POWDER-FREE SURGICAL GLOVESSep 29, 2011
90 days to decisionK111878 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k111878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 1, 2011
Decision date	Sep 29, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardinal Health, Inc.
Location	Waukegan, IL, US
Contact	TATYANA BOGDAN
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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