

**K121897 PROTEXIS LATEX BASIC STERILE POWDER-FREE  
SURGICAL GLOVES**Jul 27, 2012  
28 days to decisionK121897 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k121897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Jun 29, 2012
Decision date	Jul 27, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardinal Health, Inc.</b>
Location	Waukegan, IL, US
Contact	TATYANA BOGDAN
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k121897/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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