

**K070647 TRIFLEX SELECT**Jun 22, 2007  
106 days to decisionK070647 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k070647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Mar 8, 2007
Decision date	Jun 22, 2007
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardinal Health, Inc.</b>
Location	Waukegan, IL, US
Contact	AMY HOYD
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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