FDA 510(k) Premarket Notification

K102500 STERILE NEOPRENE POWDER-FREE SURGICAL GLOVES WITH NITRILE COATING

CLEARED

Nov 4, 2010
64 days to decision

K102500 · Product code: **KGO** · General Hospital
Source: https://www.510kdatabase.net/k102500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Sep 1, 2010
Decision date	Nov 4, 2010
Days to decision	64 days
Third-party review	Yes
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102500/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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