FDA 510(k) Premarket Notification

K093300 ESTEEM SMT POLYISOPRENE POWDER-FREE SURGICAL STERILE GLOVES

CLEARED

Oct 30, 2009
9 days to decision

K093300 · Product code: **KGO** · General Hospital
Source: https://www.510kdatabase.net/k093300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Oct 21, 2009
Decision date	Oct 30, 2009
Days to decision	9 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/k093300/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026