

K120934 PROTEXIS LATEX BASIC STERILE LATEX POWDER-FREE SURGICAL GLOVE WITH PROTEIN CONTENT LABEL CLAIM OF 50 UG/DM OR LESSMay 23, 2012
56 days to decisionK120934 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k120934/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Mar 28, 2012 |
| Decision date | May 23, 2012 |
| Days to decision | 56 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...