

K182948 Gammex PI Hybrid Surgical Gloves Tested for Use with Chemotherapy Drugs

Mar 22, 2019
150 days to decision

K182948 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k182948/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Oct 23, 2018
Decision date	Mar 22, 2019
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ansell Healthcare Products, LLC
Location	Dothan, AL, US
Contact	Don Cronk
510(k) history	26 submissions · 26 cleared · 2005-2023

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Device record: <https://www.510kdatabase.net/k182948/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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