

K171375 Gammex PI Breach Detect Powder Free Surgical GloveFeb 6, 2018
272 days to decisionK171375 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k171375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 10, 2017
Decision date	Feb 6, 2018
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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