

K151694 Gammex PI Hybrid Surgical GlovesMar 9, 2016
260 days to decisionK151694 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k151694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 23, 2015
Decision date	Mar 9, 2016
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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