

**K053441 BIOGEL LATEX POWDER FREE STERILE
SURGEON'S GLOVE**Apr 10, 2006
122 days to decisionK053441 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k053441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Dec 9, 2005
Decision date	Apr 10, 2006
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Regent Medical Americas, LLC
Location	Norcross, GA, US
Contact	KATHLEEN HARRIS
510(k) history	7 submissions · 7 cleared · 2005-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053441/> 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 June 30, 2026