

K053442 BIOGEL SKINSENSE POLY-ISOPRENE POWDER-FREE NON-LATEX GLOVEMar 7, 2006
88 days to decisionK053442 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k053442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Dec 9, 2005
Decision date	Mar 7, 2006
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

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/k053442/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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