

K050899 BIOGEL LATEX STERILE POWDER-FREE GLOVEAug 12, 2005
123 days to decisionK050899 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k050899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 11, 2005
Decision date	Aug 12, 2005
Days to decision	123 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

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