

**K050184 BIOGEL SKINSENSE POLY-ISOPRENE POWDER-FREE NON-LATEX GLOVE**Mar 16, 2005  
48 days to decisionK050184 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k050184/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Jan 27, 2005
Decision date	Mar 16, 2005
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050184/> 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