

**K071414 BIOGEL ECLIPSE, LATEX, POWDER FREE,  
INDICATOR UNDERGLOVE WITH PROTEIN CONTENT  
LABELING CLAIM (50 MICROGRAMS OR LESS)**Sep 10, 2007  
112 days to decisionK071414 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k071414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	May 21, 2007
Decision date	Sep 10, 2007
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Molnlycke Health Care Us, LLC</b>
Location	Norcross, GA, US
Contact	STEVEN DOWDLEY
510(k) history	27 submissions · 27 cleared · 2006-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071414/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 2, 2026