

K071565 BIOGEL INDICATOR UNDERGLOVE WITH NON-PYROGENIC STATEMENTSep 10, 2007
95 days to decisionK071565 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k071565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 7, 2007
Decision date	Sep 10, 2007
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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