

K101163 BIOGEL ORTHOPRO INDICATOR UNDERGLOVENov 23, 2010
211 days to decisionK101163 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k101163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 26, 2010
Decision date	Nov 23, 2010
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Molnlycke Health Care USA
Location	Norcross, GA, US
Contact	ANGELA BUNN
510(k) history	1 submissions · 1 cleared · 2010-2010

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