

**K071465 BIOGEL ORTHOPAEDIC SURGICAL GLOVE WITH
NON-PRYOGENIC STATEMENT**Sep 11, 2007
105 days to decisionK071465 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k071465/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | May 29, 2007 |
| Decision date | Sep 11, 2007 |
| Days to decision | 105 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/k071465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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