

**K140477 BIOGEL PS SURGICAL GLOVE SERIES, BIOGEL  
SKINSENSE SURGICAL GLOVE SERIES**Mar 23, 2015  
390 days to decisionK140477 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k140477/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Surgeon&apos;s Gloves (KGO)        |
| Date received         | Feb 26, 2014                       |
| Decision date         | Mar 23, 2015                       |
| Days to decision      | 390 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140477/>. 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 2, 2026