

K151607 Finessis Zero Flexylon Powder Free Sterile White Surgical GloveNov 16, 2015
154 days to decisionK151607 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k151607/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Jun 15, 2015 |
| Decision date | Nov 16, 2015 |
| Days to decision | 154 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lucenia Prescience AG |
| Location | Baar, CH |
| Contact | Robert Hill |
| 510(k) history | 9 submissions · 9 cleared · 2013-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151607/>. 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 May 30, 2026