

**K131751 FINESSIS VIOLET ELEMENT POLYISOPRENE
POWDERFREE STERILE SURGICAL GLOVES**Sep 25, 2013
103 days to decisionK131751 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k131751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 14, 2013
Decision date	Sep 25, 2013
Days to decision	103 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/k131751/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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