

K231446 Single-Use Latex Sterile Surgical Gloves (SG100)Sep 22, 2023
127 days to decisionK231446 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k231446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 18, 2023
Decision date	Sep 22, 2023
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fitone Latex Products Co., Ltd. Guangdong
Location	Zhanjiang, CN
Contact	Christine Ou
510(k) history	4 submissions · 4 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231446/> 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 25, 2026