

**K230217 Sterile Polyisoprene Powder Free Surgical Glove,
Tested for Use with Chemotherapy Drugs**May 13, 2023
107 days to decisionK230217 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k230217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jan 26, 2023
Decision date	May 13, 2023
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Grand Work Plastic Products Co., Ltd.
Location	Zanhuang County, CN
Contact	Wu Yuli
510(k) history	19 submissions · 19 cleared · 2004-2023

REGULATORY CONSULTANT

Consulting firm	Hongray USA Medical Products, Inc.
Contact	Kathy Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230217/>; 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 13, 2026