

**K222058 Polyisoprene Surgical Glove, Powder Free, Sterile,
Tested for Use with Chemotherapy Drugs and Fentanyl
Resistant**Oct 22, 2022
102 days to decisionK222058 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k222058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 12, 2022
Decision date	Oct 22, 2022
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wrp Asia Pacific Sdn. Bhd.
Location	Salak Tinggi, Sepang Selangor, MY
Contact	Siti Iylia Zarith Bt Hasan
510(k) history	46 submissions · 46 cleared · 1999-2024

REGULATORY CONSULTANT

Consulting firm	Wrp USA, Inc.
Contact	Michael Scaglione

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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