

**K230578 Polyisoprene Surgical Glove (Unified Double Layer),  
Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl**Aug 31, 2023  
183 days to decisionK230578 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k230578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Mar 1, 2023
Decision date	Aug 31, 2023
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wrp Asia Pacific Sdn. Bhd.</b>
Location	Salak Tinggi, Sepang Selangor, MY
Contact	Saravanan Ramasamy
510(k) history	46 submissions · 46 cleared · 1999-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wrp USA, Inc.</b>
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)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230578/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026