

K232079 Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green)Mar 28, 2024
259 days to decisionK232079 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k232079/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 13, 2023
Decision date	Mar 28, 2024
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Natural Rubber Latex (Strip&Coat)/(Strip&Pack) Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl

APPLICANT

Company	Wrp Asia Pacific Sdn. Bhd.
Location	Salak Tinggi, Sepang Selangor, MY
Contact	Saravanan Ramasamy
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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