

**K203030 POWDER FREE NITRILE SURGICAL GLOVE, STERILE,
TESTED FOR USE WITH CHEMOTHERAPY DRUGS**Jun 11, 2021
252 days to decisionK203030 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k203030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Oct 2, 2020
Decision date	Jun 11, 2021
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

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	Saravanan Ramasamy

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/k203030/> 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