

K250313 Sterile Powder Free Synthetic Rubber Surgeon's Gloves, Green Color, Tested For Use With Chemotherapy Drugs and Gastric Acid

Aug 19, 2025
197 days to decisionK250313 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k250313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 3, 2025
Decision date	Aug 19, 2025
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Harps Europe Manufacturing GmbH
Location	Niederosterreich, AT
Contact	Alexander Weinert
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mansour Consulting, LLC
Contact	Jay Mansour

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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