

K212848 Sterile Latex Surgical Gloves Powder FreeDec 27, 2021
111 days to decisionK212848 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k212848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Sep 7, 2021
Decision date	Dec 27, 2021
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentavest Holdings Sdn Bhd
Location	Batu, MY
Contact	Teng Boon Joo
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group , Ltd.
Contact	Manoj Zacharias

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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