

K222350 Sterile Nitrile Surgical Gloves Powder FreeApr 13, 2023
253 days to decisionK222350 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k222350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Aug 3, 2022
Decision date	Apr 13, 2023
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jr Engineering & Medical Technologies (M) Sdn. Bhd.
Location	Hulu Selangor, MY
Contact	Ganesan Subramaniam
510(k) history	10 submissions · 10 cleared · 2019-2023

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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222350/> 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 25, 2026