

K221424 Sterile Surgical Powder Free Latex GloveJan 26, 2023
255 days to decisionK221424 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k221424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 16, 2022
Decision date	Jan 26, 2023
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	New Era Medicare Sdn. Bhd.
Location	Teluk Intan, MY
Contact	Fatin Nor Irdina binti Ahmad Fauzi
510(k) history	3 submissions · 3 cleared · 2022-2023

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