

**K211621 Latex Surgical Gloves, Powder Free with Protein claim
(50 micrograms or less)**Oct 6, 2021
133 days to decisionK211621 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k211621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 26, 2021
Decision date	Oct 6, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Careplus (M) Sdn Bhd
Location	Negeri Sembilan Darul Khusus, MY
Contact	Lim Kwee Shyan
510(k) history	10 submissions · 10 cleared · 2015-2021

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