

K202765 ENCORE Latex Textured Surgical Gloves, Powder Free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugsMay 27, 2021
248 days to decisionK202765 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k202765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Sep 21, 2020
Decision date	May 27, 2021
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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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