

**K210724 ENCORE Latex Acclaim, Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (50 ug/dm<sup>2</sup> per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs, GAMMEX Latex Standard, Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (50 ug/dm<sup>2</sup> per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs**

Aug 3, 2021  
146 days to decision

K210724 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k210724/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Mar 10, 2021
Decision date	Aug 3, 2021
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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