

K210656 ENCORE Latex Ortho, Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (<50µg/dm2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs, GAMMEX Latex Ortho, Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (<50 µg/dm2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

Jun 24, 2021
112 days to decision

K210656 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k210656/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Mar 4, 2021
Decision date	Jun 24, 2021
Days to decision	112 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k210656/> 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 26, 2026