

K201748 Latex Powder Free Surgical Glove with Protein Labelling Claim of 50 Microgram or Less per Gram of Glove and Tested for use with Chemotherapy DrugsOct 2, 2020
98 days to decisionK201748 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k201748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 26, 2020
Decision date	Oct 2, 2020
Days to decision	98 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	Kuan Kam Hon
510(k) history	61 submissions · 61 cleared · 1989-2020

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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