

**K214074 Latex Powder Free Surgical Glove with Protein Labeling Claim of 50 Microgram or Less per Gram of Glove and Tested for Use with Chemotherapy Drugs**

May 26, 2022  
150 days to decision

K214074 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k214074/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Dec 27, 2021
Decision date	May 26, 2022
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hartalega NGC Sdn. Bhd.</b>
Location	Bandar Sri Damansara, MY
Contact	Kuan Mun Leong
510(k) history	28 submissions · 28 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k214074/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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