

**K200897 Polyisoprene Powder Free Surgical Underglove for Use with Chemotherapy Drugs (Blue), Polyisoprene Powder Free Surgical Glove for Use with Chemotherapy Drugs (Natural)**Jun 1, 2020  
59 days to decisionK200897 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k200897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Apr 3, 2020
Decision date	Jun 1, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hartalega Sdn. Nhd</b>
Contact	Nurul Aisyah Kong

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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200897/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 18, 2026