

**K001959 POWDERED STERILE LATEX SURGICAL GLOVE,  
WITH PROTEIN CONTENT LABELING CLAIM (200  
MICROGRAMS OR LESS)**

Jul 26, 2000  
29 days to decision

K001959 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k001959/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Jun 27, 2000
Decision date	Jul 26, 2000
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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

Device record: <https://www.510kdatabase.net/k001959/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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