

**K011066 STERILE LATEX SURGICAL GLOVES (POWDERED)  
WITH PROTEIN CONTENT LABELING CLAIM (100  
MICROGRAMS OR LESS)**Sep 11, 2001  
155 days to decisionK011066 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k011066/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Apr 9, 2001
Decision date	Sep 11, 2001
Days to decision	155 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Smart Glove Corp. Sdn Bhd</b>
Location	Klang Selangor, MY
Contact	NG-YEW SOON
510(k) history	27 submissions · 27 cleared · 1998-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011066/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026