

**K954002 AMPRI**Jan 29, 1996  
157 days to decisionK954002 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k954002/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Aug 25, 1995
Decision date	Jan 29, 1996
Days to decision	157 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ampri Rubberware Industries Sdn Bhd</b>
Location	Lumpur, Malaysia, MY
Contact	MAY PHNG
510(k) history	8 submissions · 8 cleared · 1989-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954002/> 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 4, 2026