

**K935464 COMFIT**May 9, 1994  
178 days to decisionK935464 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k935464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Nov 12, 1993
Decision date	May 9, 1994
Days to decision	178 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Wembley Rubber Products (M) Sdn Bhd</b>
Location	Kuala Lumpur, Malaysia, MY
Contact	ONG GHEE CHEE
510(k) history	61 submissions · 61 cleared · 1990-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935464/> 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 May 26, 2026