

K170152 POLYCHLOROPRENE POWDER FREE SURGICAL GLOVE (GREEN)May 5, 2017
108 days to decisionK170152 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k170152/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jan 17, 2017
Decision date	May 5, 2017
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170152/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026