

K160928 Latex Polymer Coated Powder Free Surgical Glove with Protein Labeling Claim of 50 microgram or Less per Gram of Glove (Natural), Latex Polymer Coated Powder Free Surgical Glove with Protein Labeling Claim of 50 microgram or Less per Gram of Glove (Green)Dec 20, 2016
260 days to decisionK160928 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k160928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 4, 2016
Decision date	Dec 20, 2016
Days to decision	260 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdb. Bhd.
Location	Bandar Sri Damansara, MY
Contact	KUAN KAM HON
510(k) history	4 submissions · 4 cleared · 2014-2017

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