

K161006 Latex Powder Free Polymer Coated Examination Glove with Protein Labeling Claim of 50 Microgram or Less Per Gram of GloveAug 4, 2016
115 days to decisionK161006 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k161006/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 11, 2016
Decision date	Aug 4, 2016
Days to decision	115 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

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