

K133953 LATEX POWDER FREE EXAMINATION GLOVES WITH COLLOIDAL OATMEAL USP SKIN PROTECTANT DRUG WITH PROTEIN LABELING CLAIM OF 50 MMay 28, 2014
156 days to decisionK133953 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k133953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 23, 2013
Decision date	May 28, 2014
Days to decision	156 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	NURUL AISYAH KONG BT ABDULLAH
510(k) history	61 submissions · 61 cleared · 1989-2020

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