

**K013537 ROYAL IMPERIAL POWDERED LATEX EXAMINATION
GLOVES WITH PROTEIN CONTENT LABELING CLAIM (200
MICROGRAMS OR LESS)**Dec 7, 2001
45 days to decisionK013537 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k013537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 23, 2001
Decision date	Dec 7, 2001
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Koon Seng Sdn Bhd
Location	81707 Pasir Gudang, Johor, MY
Contact	LIM WENG HENG
510(k) history	7 submissions · 7 cleared · 1989-2021

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