

**K001165 POLYMER COATED POWDER FREE, LATEX
EXAMINATION GLOVES WITH PROTEIN CONTENT LABELING
CLAIM (50 MICROGRAMS OR LESS)**Jul 5, 2000
86 days to decisionK001165 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k001165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 10, 2000
Decision date	Jul 5, 2000
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medipure Corporation (M) Sdn. Bhd.
Location	Kuala Kangsar, Perak, MY
Contact	LEE SON HONG
510(k) history	2 submissions · 2 cleared · 2000-2006

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