

**K010054 GUTHRIE SHIELD BLUE LATEX EXAMINATION
GLOVES, POWDERED WITH PROTEIN CONTENT LABELING
CLAIM (200 MICROGRAMS OR LESS)**Jan 26, 2001
18 days to decisionK010054 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k010054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 8, 2001
Decision date	Jan 26, 2001
Days to decision	18 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Guthrie Medicare Products (Melaka) Sdn Bhd
Location	Kelemak, Alor Gajah, Melaka, MY
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	12 submissions · 12 cleared · 1991-2001

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