

**K001216 POWDER-FREE LATEX EXAMINATION GLOVE
STERILE WITH OPTIONAL PROTEIN LABELING CLAIM (50
MICROGRAMS OR LESS)**Apr 28, 2000
14 days to decisionK001216 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k001216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 14, 2000
Decision date	Apr 28, 2000
Days to decision	14 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fitco Dipped Products Pvt., Ltd.
Location	Kerala, IN
Contact	JOSEPH J E PEREIRA
510(k) history	6 submissions · 6 cleared · 1999-2000

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