

**K013821 SILK TOUCH POWDERED LATEX EXAMINATION
GLOVE WITH PROTEIN CONTENT LABELING CLAIM (200
MICROGRAMS OR LESS)**Mar 5, 2002
109 days to decisionK013821 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k013821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 16, 2001
Decision date	Mar 5, 2002
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Top Quality Mfg., Inc.
Location	New Port Riche, FL, US
Contact	MARC SINKOW
510(k) history	4 submissions · 4 cleared · 2000-2002

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