

K942643 ENSURE POWDER-FREE LATEX PATIENT EXAMINATION GLOVESOct 7, 1994
126 days to decisionK942643 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k942643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 3, 1994
Decision date	Oct 7, 1994
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Basic Intl., Inc.
Location	Great Neck,, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	1 submissions · 1 cleared · 1994-1994

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