

K011045 TEXTURED POWDER-FREE LATEX EXAMINATION GLOVES CONTAINS 50 MICROGRAMS OR LESS OF TOTAL WATER EXTRACTABLE PROTEIN PER GRAMSep 11, 2001
159 days to decisionK011045 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k011045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 5, 2001
Decision date	Sep 11, 2001
Days to decision	159 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shen Wei (Usa), Inc.
Location	Foster City, CA, US
Contact	BELLE CHOU
510(k) history	58 submissions · 58 cleared · 1989-2022

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