

**K011407 LATEX POWDER-FREE EXAMINATION GLOVES BLUE,
POLYMER COATED, CONTAINS 50 MICROGRAMS OR LESS OF
TOTAL WATER EXTRACTABLE PRO**Sep 11, 2001
145 days to decisionK011407 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k011407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 19, 2001
Decision date	Sep 11, 2001
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sempermed USA, Inc.
Location	Palm Harbor, FL, US
Contact	KATIE LEVINSON
510(k) history	2 submissions · 2 cleared · 2001-2001

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