

**K011377 NON-STERILE POWDER-FREE BLUE LATEX
EXAMINATION GLOVES, WITH AND WITHOUT BUBBLEGUM
SCENTING & A PROTEIN LABELING CLAIM (5)**Jun 7, 2001
34 days to decisionK011377 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k011377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 4, 2001
Decision date	Jun 7, 2001
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sgmp Co., Ltd.
Location	Sparks, NV, US
Contact	JANNA P TUCKER
510(k) history	31 submissions · 31 cleared · 2000-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011377/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 2, 2026