

**K011749 LATEX POWDERED PATIENT EXAMINATION GLOVE,  
200 MICROGRAMS OR LESS**Aug 22, 2001  
83 days to decisionK011749 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k011749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 31, 2001
Decision date	Aug 22, 2001
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011749/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 3, 2026