

**K000217 ROYAL SHIELD NON-STERILE PURPLE (PINK/BLUE)  
COLORED POWDERED LATEX EXAM WITH PROTEIN  
LABELING CLAIM [<200 MCG OR LESS] W**Feb 18, 2000  
25 days to decisionK000217 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k000217/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 24, 2000
Decision date	Feb 18, 2000
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shield Gloves Manufacturer (M) Sdn Bhd</b>
Location	Petaling Jaya, MY
Contact	JANNA P TUCKER
510(k) history	18 submissions · 18 cleared · 1994-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000217/>; 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