

**K003545 NUGARD POWDERFREE, BLUE POLYMER COATED  
LATEX EXAMINATION GLOVES WITH PROTEIN CONTENT  
LABELING CLAIM (50 MICROGRAMS OR LE**Dec 21, 2000  
34 days to decisionK003545 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k003545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 17, 2000
Decision date	Dec 21, 2000
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terang Nusa Sdn Bhd</b>
Location	68100 Batu Caves Selangor, MY
Contact	CHIN-GUAN LOW
510(k) history	26 submissions · 26 cleared · 1989-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003545/>; 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 2, 2026