

**K083337 NUGARD, SENSIFLEX PROCEDURE EXAMINATION  
GLOVES**Jan 27, 2009  
76 days to decisionK083337 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k083337/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 12, 2008
Decision date	Jan 27, 2009
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Terang Nusa Sdn Bhd</b>
Location	68100 Batu Caves Selangor, MY
Contact	ROBERT HILL
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/k083337/> 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](http://accessdata.fda.gov). - Generated June 1, 2026