

**K892478 SAFETEX & SUNTEX PATIENT EXAMINATION  
GLOVES**May 8, 1989  
31 days to decisionK892478 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k892478/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 7, 1989
Decision date	May 8, 1989
Days to decision	31 days
Third-party review	No

**APPLICANT**

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Company	<b>P.T. Latexindo Prautama</b>
Location	Chester, NJ, US
Contact	ROBERT S KENNEDY
510(k) history	3 submissions · 3 cleared · 1989-1991

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892478/>; 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 7, 2026