

K893331 LATEX EXAMINATION GLOVESJul 14, 1989
86 days to decisionK893331 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k893331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 19, 1989
Decision date	Jul 14, 1989
Days to decision	86 days
Third-party review	No

APPLICANT

Company	P.T. Kencana Ronasakti Prima
Location	Great Neck, NY, US
Contact	ALAN P SCHWARTZ
510(k) history	1 submissions · 1 cleared · 1989-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893331/>, 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. - Generated July 8, 2026