

K913776 PATIENT EXAMINATION GLOVESNov 7, 1991
86 days to decisionK913776 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k913776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 13, 1991
Decision date	Nov 7, 1991
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	P.T. Irama Dinamika Latex
Location	Medan - Indonesia, ID
Contact	VENKATESAN
510(k) history	11 submissions · 11 cleared · 1991-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913776/> 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 5, 2026