

**K962518 NITRILE COPOLYMER PATIENT EXAMINATION  
GLOVES**Dec 19, 1996  
175 days to decisionK962518 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k962518/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 27, 1996
Decision date	Dec 19, 1996
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>P.T. Irama Dinamika Latex</b>
Location	Medan - Indonesia, ID
Contact	ANIL TANEJA
510(k) history	11 submissions · 11 cleared · 1991-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962518/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated July 4, 2026