

**K972306 POWDERFREE COLORED AND FLAVORED NITRILE
COPOLYMER PATIENT EXAMINATION GLOVES-MEDICAL
DEVICE**Sep 12, 1997
85 days to decisionK972306 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k972306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 19, 1997
Decision date	Sep 12, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972306/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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