

**K981064 POWDERFREE COLORED AND FLAVORED  
CHLOROPRENE PATIENT EXAMINATION GLOVES**

Nov 5, 1998  
227 days to decision

K981064 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k981064/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 23, 1998
Decision date	Nov 5, 1998
Days to decision	227 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/k981064/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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