

K963771 CHLOROPRENE EXAM GLOVESDec 19, 1996
91 days to decisionK963771 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k963771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 19, 1996
Decision date	Dec 19, 1996
Days to decision	91 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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