

K970216 NITRILE EXAMINATION GLOVES-PRE POWDEREDSep 26, 1997
253 days to decisionK970216 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k970216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 16, 1997
Decision date	Sep 26, 1997
Days to decision	253 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Influx Pacific Sdn. Bhd.
Location	Malacca, West Malaysia, MY
Contact	GAN SOONG TEE
510(k) history	5 submissions · 5 cleared · 1989-1998

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