

K982218 NITRILE POWDER-FREE UNISEAL GLOVESNov 30, 1998
159 days to decisionK982218 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k982218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 24, 1998
Decision date	Nov 30, 1998
Days to decision	159 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	American Healthcare Products (M) Sdn Bhd
Location	Nilai, Negeri Sembilan 71800, MY
Contact	TARANI DEVI
510(k) history	3 submissions · 3 cleared · 1998-1999

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