

K964148 PATIENT EXAMINATION GLOVESFeb 7, 1997
114 days to decisionK964148 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k964148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 16, 1996
Decision date	Feb 7, 1997
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement
Other names	CHLORINATED POWDERFREE NITRILE EXAMINATION GLOVES

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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