

K170397 Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Polymer Coated, Tested for Use with Chemotherapy DrugsJul 10, 2017
151 days to decisionK170397 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k170397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 9, 2017
Decision date	Jul 10, 2017
Days to decision	151 days
Third-party review	No
Summary / Statement	Statement
Other names	Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Polymer Coated, Tested for Use with Chemotherapy Drugs

APPLICANT

Company	Kossan International Sdn Bhd
Location	Klang, MY
Contact	Cho Sow Fong
510(k) history	12 submissions · 12 cleared · 2015-2026

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