

K183287 Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl CitrateApr 5, 2019
130 days to decisionK183287 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k183287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 26, 2018
Decision date	Apr 5, 2019
Days to decision	130 days
Third-party review	No
Summary / Statement	Statement
Other names	Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

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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