

K232461 Powder Free Nitrile Examination Glove, Pink Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl CitrateNov 14, 2023
91 days to decisionK232461 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k232461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 15, 2023
Decision date	Nov 14, 2023
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Powder Free Nitrile Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Examination Glove, Black Colored, Non-Sterile, Low Dermatitis

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232461/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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