

K223375 Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-sterile, Low Dermatitis Potential. Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.Mar 15, 2023
131 days to decisionK223375 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 4, 2022
Decision date	Mar 15, 2023
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Kossan International Sdn Bhd3
Location	Klang, MY
Contact	Cho Sow Fong
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223375/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026