

K181857 Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential. Tested for Use with Chemotherapy Drugs and Fentanyl CitrateNov 20, 2018
132 days to decisionK181857 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k181857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 11, 2018
Decision date	Nov 20, 2018
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

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/k181857/> 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 24, 2026