

**K162095 Non-Sterile, Powder Free Nitrile Examination Gloves,
Tested for use with Chemotherapy Drugs (Original Blue, Cobalt
Blue)**Nov 2, 2016
97 days to decisionK162095 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k162095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 28, 2016
Decision date	Nov 2, 2016
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Yty Industry (Manjung) Sdn Bhd
Location	Selangor, Malaysia, MY
Contact	Punitha Samy
510(k) history	27 submissions · 27 cleared · 1989-2023

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