

K210755 Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Blue)

May 7, 2021
53 days to decision

K210755 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210755/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 15, 2021
Decision date	May 7, 2021
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meditech Gloves Sdn Bhd
Location	Nilai, MY
Contact	Effendi Tenang
510(k) history	2 submissions · 2 cleared · 2021-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k210755/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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