

**K221378 Nitrile Powder Free Blue Patient Examination Gloves,
Non-Sterile**Sep 30, 2022
141 days to decisionK221378 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 12, 2022
Decision date	Sep 30, 2022
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tec Gloves Industry (M) Sdn.Bhd.
Location	Klang, MY
Contact	Eunice Arumugam
510(k) history	1 submissions · 1 cleared · 2022-2022

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