

K212804 Powder free nitrile examination glove- blue, non-sterileDec 1, 2021
90 days to decisionK212804 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 2, 2021
Decision date	Dec 1, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hong Seng Gloves Sdn Bhd
Location	Sungai Petani, MY
Contact	Ho Chia Yao
510(k) history	4 submissions · 4 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Emergo Global Representative, LLC
Contact	Michael Van Der Woude

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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