

**K212535 Nitrile Powder Free Blue Examination Gloves, Non-Sterile**Dec 4, 2021  
115 days to decisionK212535 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212535/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 11, 2021
Decision date	Dec 4, 2021
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Mah Sing Healthcare Sdn. Bhd.</b>
Location	Kuala Lumpur, MY
Contact	Azlan Hashim
510(k) history	5 submissions · 5 cleared · 2021-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212535/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026