

K220232 Nitrile Powder Free Examination Gloves, Non-Sterile - Blue, Black, OrangeFeb 20, 2022
24 days to decisionK220232 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 27, 2022
Decision date	Feb 20, 2022
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Megine Industries Sdn Bhd
Location	Kuala Lumpur, MY
Contact	Benjamin Ng Soong Jing
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220232/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026