

**K222349 JR MEDIC Nitrile Examination Gloves Powder Free
(Orange, Purple)**Oct 21, 2022
79 days to decisionK222349 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k222349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 3, 2022
Decision date	Oct 21, 2022
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jr Engineering & Medical Technologies (M) Sdn. Bhd.
Location	Hulu Selangor, MY
Contact	Ganesan Subramaniam
510(k) history	10 submissions · 10 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group , Ltd.
Contact	Manoj Zacharias

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222349/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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