

K222531 Synthetic Polymer Glove - Polyethylene (Black)Jan 22, 2023
153 days to decisionK222531 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k222531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 22, 2022
Decision date	Jan 22, 2023
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ur Industry Sdn Bhd
Location	Senai, MY
Contact	Chua Song Han
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Integrated Assessment Services Pvt, Ltd.
Contact	A.C. Thirumaran

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/k222531/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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