

K210330 Powder Free Black Nitrile Examination Gloves, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl ResistantMar 4, 2022
393 days to decisionK210330 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 4, 2021
Decision date	Mar 4, 2022
Days to decision	393 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wrp Asia Pacific Sdn. Bhd.
Location	Salak Tinggi, Sepang Selangor, MY
Contact	Zahari Bin Darus
510(k) history	46 submissions · 46 cleared · 1999-2024

REGULATORY CONSULTANT

Consulting firm	Wrp USA, Inc.
Contact	Saravanan Ramasamy

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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