

K213142 Biodegradable Powder Free Flock-Lined Nitrile Examination Glove, Black and Gray Colors, Tested for use with Chemotherapy drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl Citrate Simulated Gastric Acid SolutionJan 28, 2022
123 days to decisionK213142 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k213142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 27, 2021
Decision date	Jan 28, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shen Wei (Usa), Inc.
Location	Foster City, CA, US
Contact	Cheryl Reep
510(k) history	58 submissions · 58 cleared · 1989-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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