

**K213141 Biodegradable Powder Free Nitrile Examination Glove, Blue and Green colors, Low Dermatitis Potential, Tested for use with Chemotherapy drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl Citrate-Simulated Gastric Acid Solution**May 28, 2022  
243 days to decisionK213141 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k213141/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 27, 2021
Decision date	May 28, 2022
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213141/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026