

**K202086 Biodegradable Powder Free Nitrile Examination Glove,  
Low Dermatitis,Potential Claim, Blue, Green, Black, White,  
Orange, Black-White, Teal-Gray, White-Green, White-Orange,  
White-Blue, Blue-White, Green-White, Orange-White Colors**Mar 16, 2021  
232 days to decisionK202086 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k202086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 27, 2020
Decision date	Mar 16, 2021
Days to decision	232 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/k202086/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026