

K202080 Biodegradable Powder Free Nitroprene Examination Glove, Low Dermatitis Potential Claim, Teal-Black ColorMar 24, 2021
240 days to decisionK202080 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k202080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 27, 2020
Decision date	Mar 24, 2021
Days to decision	240 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/k202080/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026