

K964628 NITRILE POWDER-FREE EXAMINATION GLOVESFeb 10, 1997
83 days to decisionK964628 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k964628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 19, 1996
Decision date	Feb 10, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964628/> 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 15, 2026