

**K011961 POWDER-FREE BUTADIENE COPOLYMER EXAM  
GLOVES WITH ALOE, VITAMINS E PH5.5**

Sep 26, 2001  
96 days to decision

K011961 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k011961/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 22, 2001
Decision date	Sep 26, 2001
Days to decision	96 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k011961/> 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