

**K190466 PF Nitrile Exam Glove with pH coating, Black-Gray & White-Black Colors, Tested for Use with chemotherapy drugs and Fentanyl Citrate**Sep 26, 2019  
212 days to decisionK190466 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k190466/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 26, 2019
Decision date	Sep 26, 2019
Days to decision	212 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190466/>; 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 15, 2026