

**K093516 NITRITECH OR MULTIPLE PRIVATE LABEL NON
STERILE POWDERED NITRILE EXAMINATION GLOVES**Jun 29, 2010
228 days to decisionK093516 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k093516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 13, 2009
Decision date	Jun 29, 2010
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Summit Glove, Inc.
Location	Minerva, OH, US
Contact	JAMES MOORE
510(k) history	5 submissions · 5 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093516/> 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 26, 2026