

K243796 GLOVEONE™ Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl]

Jun 3, 2025
175 days to decision

K243796 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243796/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 10, 2024
Decision date	Jun 3, 2025
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Glove One, LLC
Location	Mooresville, NC, US
Contact	Jason Palmer
Website	https://www.gloveone.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Glove One, LLC is an American manufacturer of nitrile examination gloves based in Greenville, South Carolina. The company specializes in producing General Hospital devices, specifically powder-free nitrile gloves formulated for medical and protective applications. Glove One is a subsidiary of Health Supply US and operates a state-of-the-art manufacturing facility designed to produce over 4 billion gloves annually. The company has received FDA 510(k) clearance from total submission since 2025. Glove One's cleared device includes powder-free nitrile examination gloves teste...

REGULATORY CONSULTANT

Consulting firm	Terrie M Heidemann
Contact	Terrie M Heidemann

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k243796/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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