

**K211360 Disposable Nitrile Powder Free Examination Gloves
(Non-sterile)**Jan 15, 2022
257 days to decisionK211360 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 3, 2021
Decision date	Jan 15, 2022
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Universal Gloves
Location	Medan, ID
Contact	Sutopo Sutopo
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Ammex Corporation
Contact	Sasitharan Nair

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211360/>. 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