

K211540 Edma Synthetic Nitrile Examination GlovesAug 9, 2021
82 days to decisionK211540 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 19, 2021
Decision date	Aug 9, 2021
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edma Group, LLC
Location	Phoenix, AZ, US
Contact	Vio Cretu
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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/k211540/> 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 25, 2026