

K211457 Powder Free Nitrile Examination Gloves (Blue, Black, Indigo)Dec 18, 2021
221 days to decisionK211457 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 11, 2021
Decision date	Dec 18, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ammex Corporation
Location	Kent, WA, US
Contact	Sasitharan Nair
510(k) history	1 submissions · 1 cleared · 2021-2021

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