

K220121 Non Sterile Nitrile Powder Free Examination Gloves – Blue, Green, and Black

Apr 11, 2022
83 days to decision

K220121 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220121/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 18, 2022
Decision date	Apr 11, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aamedix Glove Sdn Bhd
Location	Selanger Darul Ehsan, MY
Contact	Annette Schaps
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220121/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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