

K201428 Powder Free Black Nitrile Examination Glove

Jun 24, 2021
391 days to decision

K201428 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k201428/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 29, 2020
Decision date	Jun 24, 2021
Days to decision	391 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vietglove Corporation
Location	Bau Bang Province, VN
Contact	Pham Ngoc Thanh
510(k) history	4 submissions · 4 cleared · 2016-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k201428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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