

K211390 Nitrile Blue Powder-free Examination GloveAug 28, 2021
115 days to decisionK211390 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k211390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 5, 2021
Decision date	Aug 28, 2021
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Cardinal Health200, LLC
Location	Waukegan, IL, US
Contact	William Cisneros
510(k) history	26 submissions · 26 cleared · 2011-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211390/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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