

K203036 Non Sterile Powder Free Polyurethane Examination Gloves (Blue and Black colors)May 7, 2021
214 days to decisionK203036 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k203036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 5, 2020
Decision date	May 7, 2021
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Central Medicare Sdn Bhd
Location	Diamond Bar, CA, US
Contact	Fatin Nor Irdina Bt Ahmad Fauzi
510(k) history	15 submissions · 15 cleared · 2010-2023

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