

K183354 Powder Free Blue Nitrile Examination Gloves Tested for use with 32 Chemotherapy Drugs and Fentanyl CitrateJun 20, 2019
199 days to decisionK183354 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k183354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 3, 2018
Decision date	Jun 20, 2019
Days to decision	199 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gx Corporation Sdn Bhd
Location	Klang, Selangor, MY
Contact	Khon Pu Foo
510(k) history	18 submissions · 18 cleared · 2007-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183354/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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