

K230681 Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs, with Gastric Acid and Fentanyl

Oct 2, 2023
203 days to decision

K230681 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k230681/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 13, 2023
Decision date	Oct 2, 2023
Days to decision	203 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Central Medicare Sdn Bhd
Location	Diamond Bar, CA, US
Contact	Chua Kah Ying
510(k) history	15 submissions · 15 cleared · 2010-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k230681/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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