

K213373 Powder-Free Green Biodegradable Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl CitrateMar 10, 2022
149 days to decisionK213373 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 12, 2021
Decision date	Mar 10, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Smart Glove Corporation Sdn. Bhd.
Location	Klang, MY
Contact	Lim Chin Keong
510(k) history	5 submissions · 5 cleared · 2017-2022

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