

K221773 Blue Nitrile Powder Free Patient Examination Glove, Non-Sterile, Tested For Use With the Opioid Fentanyl Citrate, Simulated Gastric Acid, and Fentanyl In Gastric AcidJul 30, 2022
39 days to decisionK221773 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221773/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 21, 2022
Decision date	Jul 30, 2022
Days to decision	39 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Onetexx Sdn Bhd
Location	Kamunting, MY
Contact	Freddy Low
510(k) history	7 submissions · 7 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Truscott Medsci Associates, LLC
Contact	Wava Truscott

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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