FDA 510(k) Premarket Notification

CLEARED

Sep 24, 2022
54 days to decision

K222294 Black Nitrile Powder Free Patient Examination Glove, Non-Sterile, Tested for Use With Chemotherapy Drugs, the Opioid Fentanyl Citrate, simulated Gastric Acid, and Fentanyl In Gastric Acid

K222294 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k222294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 1, 2022
Decision date	Sep 24, 2022
Days to decision	54 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