

K211816 Brightway Brand, Nitrile Examination Gloves, Powder Free (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Nov 2, 2022
509 days to decision

K211816 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211816/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 11, 2021
Decision date	Nov 2, 2022
Days to decision	509 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brightway Holdings Sdn. Bhd.
Location	Klang, Selangor Darul Ehsan, MY
Contact	G. Baskaran
510(k) history	24 submissions · 24 cleared · 1999-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k211816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026