

K254285 Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue

Jul 20, 2026
201 days to decision

K254285 · Product code: LZA · General Hospital
Source: <https://www.510kdatabase.net/k254285/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 31, 2025
Decision date	Jul 20, 2026
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary
Other names	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Violet Blue

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	Kuan Mun Leong
510(k) history	31 submissions · 31 cleared · 2014-2026