

K180786 Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs Aqua Blue (ABLU), Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs Violet Blue (VBLU) - Extended CuffNov 2, 2018
221 days to decisionK180786 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k180786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 26, 2018
Decision date	Nov 2, 2018
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	Kuan Kam Hon
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180786/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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