

K201857 Powder Free Nitrile Examination Glove Black and Dual Color White-BlueAug 20, 2021
410 days to decisionK201857 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k201857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 6, 2020
Decision date	Aug 20, 2021
Days to decision	410 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Careplus (M) Sdn Bhd
Location	Negeri Sembilan Darul Khusus, MY
Contact	Lim Kwee Shyan
510(k) history	10 submissions · 10 cleared · 2015-2021

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