

K221667 Non Sterile Powder Free Latex Examination GloveOct 28, 2022
142 days to decision

K221667 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k221667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 8, 2022
Decision date	Oct 28, 2022
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	New Era Medicare Sdn. Bhd.
Location	Teluk Intan, MY
Contact	Fatin Nor Irdina binti Ahmad Fauzi
510(k) history	3 submissions · 3 cleared · 2022-2023

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