

K183441 Powder-free Nitrile Patient Examination Glove, Green Colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy DrugsOct 4, 2019
296 days to decisionK183441 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k183441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 12, 2018
Decision date	Oct 4, 2019
Days to decision	296 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Semperit Investments Asia Pte , Ltd.
Location	Singapore, SG
Contact	Andreas Woess
510(k) history	4 submissions · 4 cleared · 2017-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183441/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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