

K171378 Non-Sterile, Single use, Powder-free examination glove tested for use with Chemotherapy drugsSep 14, 2017
127 days to decisionK171378 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k171378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 10, 2017
Decision date	Sep 14, 2017
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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