

K212645 ATDec 16, 2021
118 days to decisionK212645 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 20, 2021
Decision date	Dec 16, 2021
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	At Glove Engineering Sdn. Bhd
Location	Kawasan Perusahaan Keramik Chepor, MY
Contact	L. A. Choong
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group Limited
Contact	Manoj Zacharias

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212645/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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