

K222342 Betel Gloves Nitrile Examination Glove Powder FreeSep 24, 2022
52 days to decisionK222342 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k222342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 3, 2022
Decision date	Sep 24, 2022
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Betel Care Sdn. Bhd.
Location	Selangor Darul Ehsan, MY
Contact	Abdul Rahman Richard Abdullah
510(k) history	4 submissions · 4 cleared · 2000-2022

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/k222342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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