

K211477 Latex Examination Powder Free GlovesSep 20, 2021
131 days to decisionK211477 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k211477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 12, 2021
Decision date	Sep 20, 2021
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aspen Glove Sdn. Bhd.
Location	Georgetown, MY
Contact	Iskandar Basha bin Abdul Kadir
510(k) history	4 submissions · 4 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Liberty Mangement Group , Ltd.
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/k211477/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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