

K213076 AspenMed+Dec 20, 2021
88 days to decisionK213076 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k213076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Medical Glove, Specialty (LZC)
Date received	Sep 23, 2021
Decision date	Dec 20, 2021
Days to decision	88 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 Management Group , Ltd.
Contact	Manoj Zacharias

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

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