

K221157 JR MedicAug 30, 2022
131 days to decisionK221157 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k221157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Medical Glove, Specialty (LZC)
Date received	Apr 21, 2022
Decision date	Aug 30, 2022
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jr Engineering & Medical Technologies (M) Sdn. Bhd.
Location	Hulu Selangor, MY
Contact	Ganesan Subramaniam
510(k) history	10 submissions · 10 cleared · 2019-2023

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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