

**K230847 Chemotherapy Gloves**Sep 29, 2023  
185 days to decisionK230847 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k230847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 28, 2023
Decision date	Sep 29, 2023
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3A Glove Sdn. Bhd.</b>
Location	Senai, MY
Contact	Kumar Durarajen
510(k) history	2 submissions · 2 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle Wang

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230847/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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