

**K212847 Penta Glove**Jan 6, 2022  
121 days to decisionK212847 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 7, 2021
Decision date	Jan 6, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pentavest Holdings Sdn Bhd</b>
Location	Batu, MY
Contact	Teng Boon Joo
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Liberty Management Group , Ltd.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212847/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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