

**K223903 Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl SMALL SIZE (NGPF102)**Jan 27, 2023  
30 days to decisionK223903 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k223903/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 28, 2022
Decision date	Jan 27, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MEDIUM SIZE (NGPF103); LARGE SIZE (NGPF104); X-LARGE SIZE (NGPF105)

**APPLICANT**

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Company	<b>Semperit Investments Asia Pte , Ltd.</b>
Location	Singapore, SG
Contact	Alexander Weinert
510(k) history	4 submissions · 4 cleared · 2017-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mansour Company, LLC</b>
Contact	Jay Mansour

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

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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223903/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026