

**K212308 SHARK GLOVES Blue Nitrile Examination Gloves  
Powder Free, INCONGLOVE Blue Nitrile Examination Gloves  
Powder Free**Oct 29, 2021  
98 days to decisionK212308 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212308/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Jul 23, 2021                            |
| Decision date         | Oct 29, 2021                            |
| Days to decision      | 98 days                                 |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Srirungruang Global Co., Ltd.</b>  |
| Location       | Banbung, TH                           |
| Contact        | Suttichai Sripradub                   |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

**REGULATORY CONSULTANT**

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|-----------------|------------------------------|
| Consulting firm | <b>Mdi Consultants, Inc.</b> |
| Contact         | Aristotle Nafpliotis         |

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/k212308/> 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 25, 2026