

**K231408 Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile**Aug 11, 2023  
88 days to decisionK231408 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k231408/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | May 15, 2023                            |
| Decision date         | Aug 11, 2023                            |
| Days to decision      | 88 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shandong Intco Medical Products Co, Ltd.</b> |
| Location       | Qingzhou, CN                                    |
| Contact        | Max Li  |
| 510(k) history | 4 submissions · 4 cleared · 2022-2023           |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231408/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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