

**K213851 Disposable Medical Nitrile gloves**Mar 9, 2022  
89 days to decisionK213851 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213851/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Dec 10, 2021                            |
| Decision date         | Mar 9, 2022                             |
| Days to decision      | 89 days                                 |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|--|
| Company        | <b>Guangdong Xingcan Brothers Medical Technology Co.,Ltd</b> |
| Location       | Guangzhou, CN  |
| Contact        | Suhai Yin  |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022                        |

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>Share Info (Guangzhou) Medical Consultant , Ltd.</b> |
| Contact         | Cassie Lee  |

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/k213851/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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