

**K212639 Disposable Medical Nitrile Examination Gloves (Non sterile)**Dec 8, 2021  
110 days to decisionK212639 · Product code: **LZC** · General Hospital  
Source: <https://www.510kdatabase.net/k212639/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Medical Glove, Specialty (LZC)     |
| Date received         | Aug 20, 2021                       |
| Decision date         | Dec 8, 2021                        |
| Days to decision      | 110 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Jiangsu Nanfang Medical Co., Ltd.</b> |
| Location       | Changzhou, CN                            |
| Contact        | Xia Li                                   |
| 510(k) history | 2 submissions · 2 cleared · 2021-2022    |

**REGULATORY CONSULTANT**

---

|                 |                         |
|-----------------|-------------------------|
| Consulting firm | <b>Cnmed Consultant</b> |
| Contact         | Johnson Liu             |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212639/> 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 26, 2026