

**K211673 Disposable Medical Nitrile Gloves**Sep 1, 2021  
92 days to decisionK211673 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k211673/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Jun 1, 2021                             |
| Decision date         | Sep 1, 2021                             |
| Days to decision      | 92 days                                 |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Statement                               |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Changzhou Yihua Sanitation Material Co., Ltd.</b> |
| Location       | Changzhou, CN  |
| Contact        | Ding Jie   |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021                |

**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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211673/> 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