

K211604 Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy DrugsOct 27, 2021
155 days to decisionK211604 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211604/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | May 25, 2021 |
| Decision date | Oct 27, 2021 |
| Days to decision | 155 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Shanxi Hongjin Plastic Technology Co., Ltd. |
| Location | Linfen City, CN |
| Contact | Wu Zhigang |
| 510(k) history | 7 submissions · 7 cleared · 2018-2023 |

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Hongray USA Medical Products, Inc. |
| Contact | Kathy 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.netDevice record: <https://www.510kdatabase.net/k211604/>; Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026