

**K240361 Powder Free Green Nitrile Examination Gloves
(XS/S/M/L/XL)**Apr 4, 2024
58 days to decisionK240361 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k240361/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Feb 6, 2024 |
| Decision date | Apr 4, 2024 |
| Days to decision | 58 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Powder Free Pink Nitrile Examination Gloves (XS/S/M/L/XL); Powder Free Purple Nitrile Examination Gloves (XS/S/M/L/XL) |

APPLICANT

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|----------------|--|
| Company | Hebei Titans Hongsen Medical Technology Co., Ltd. |
| Location | Nangong, CN |
| Contact | Xiaojing Zhao |
| 510(k) history | 7 submissions · 7 cleared · 2018-2024 |

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Beijing Believe-Med Technology Service Co., Ltd. |
| Contact | Ray Wang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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