

K221143 Nitrile Exam Gloves (Blue, Black)Aug 25, 2022
127 days to decisionK221143 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221143/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Apr 20, 2022 |
| Decision date | Aug 25, 2022 |
| Days to decision | 127 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Hebei Astro Medical Supply Co., Ltd. |
| Location | Jinzhou, CN |
| Contact | Ning Zheng |
| 510(k) history | 2 submissions · 2 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------------|
| Consulting firm | Mid-Link Consulting Co, Ltd. |
| Contact | Diana Hong |

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/k221143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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