

K222498 Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)Oct 26, 2022
69 days to decisionK222498 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k222498/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Aug 18, 2022 |
| Decision date | Oct 26, 2022 |
| Days to decision | 69 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Humanwell Healthcare Group Medical Supplies Co., Ltd. |
| Location | Wuhan, CN |
| Contact | Aixue Yao |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Shanghai Sungo Management Consulting Company Limited. |
| Contact | Ivy Wang |

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/k222498/> 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