

**K100979 NITRILE EXAM GLOVE, POWDER-FREE MODEL
COLOR WHITE, NITRILE EXAM GLOVE, POWDER-FREE
MODEL COLOR BLUE**Jul 2, 2010
85 days to decisionK100979 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k100979/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Apr 8, 2010 |
| Decision date | Jul 2, 2010 |
| Days to decision | 85 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Jiangsu Sunshine Plastic Products, Co., Ltd. |
| Location | Taipei County, TW |
| Contact | MICHAEL LEE |
| 510(k) history | 4 submissions · 4 cleared · 2010-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100979/>; 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 June 20, 2026