

K100369 POWDER-FREE NITRILE GLOVES, BLACKMay 20, 2010
97 days to decisionK100369 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k100369/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Feb 12, 2010 |
| Decision date | May 20, 2010 |
| Days to decision | 97 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | HI Rubber Industries Sdn Bhd |
| Location | Kuala Pilah, Negeri Sembilan, MY |
| Contact | LAU SIONG HUT |
| 510(k) history | 7 submissions · 7 cleared · 2007-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100369/> 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 27, 2026