

K984615 POWDERED NITRILE EXAMINATION GLOVESFeb 17, 1999
50 days to decisionK984615 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k984615/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Dec 29, 1998 |
| Decision date | Feb 17, 1999 |
| Days to decision | 50 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Shiva Medicare , Ltd. |
| Location | Crofton, MD, US |
| Contact | JAMES F LOGAN |
| 510(k) history | 5 submissions · 5 cleared · 1998-1999 |

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