

**K981349 SMART-FEEL POWDER FREE NITRILE EXAMINATION GLOVES**

May 18, 1998  
38 days to decision

K981349 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k981349/>

**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Apr 10, 1998                            |
| Decision date         | May 18, 1998                            |
| Days to decision      | 38 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Statement                               |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Smart Glove Corp. Sdn Bhd</b>        |
| Location       | Klang Selangor, MY                      |
| Contact        | FOO KHON PU                             |
| 510(k) history | 27 submissions · 27 cleared · 1998-2009 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k981349/> 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 July 2, 2026