

**K993311 COMFIT POWDER FREE NITRILE EXAMINATION  
GLOVE, STERILE**

Nov 19, 1999  
46 days to decision

K993311 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k993311/>

**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Oct 4, 1999                             |
| Decision date         | Nov 19, 1999                            |
| Days to decision      | 46 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Wrp Asia Pacific Sdn. Bhd.</b>       |
| Location       | Salak Tinggi, Sepang Selangor, MY       |
| Contact        | YUE WAH CHOW                            |
| 510(k) history | 46 submissions · 46 cleared · 1999-2024 |

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

Device record: <https://www.510kdatabase.net/k993311/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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