

**K001065 DISPOSABLE POWDERED NITRILE EXAM GLOVE,  
BLUE COLOR**

May 23, 2000  
50 days to decision

K001065 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k001065/>

**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Apr 3, 2000                             |
| Decision date         | May 23, 2000                            |
| Days to decision      | 50 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Statement                               |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Sheen More Ent. Co., Ltd.</b>      |
| Location       | Tou-Liu, Yun-Lin, TW                  |
| Contact        | KEN HUANG                             |
| 510(k) history | 6 submissions · 6 cleared · 1999-2002 |

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

Device record: <https://www.510kdatabase.net/k001065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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