

**K093500 POWDER FREE NITRILE EXAMINATION GLOVES,
WHITE (NON-COLORED) OR BLUE (COLORED), NON-STERILE**Jan 19, 2010
68 days to decisionK093500 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k093500/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Medical Glove, Specialty (LZC) |
| Date received | Nov 12, 2009 |
| Decision date | Jan 19, 2010 |
| Days to decision | 68 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Wear Safe Malaysia Sdn. Bhd. |
| Location | Port Klang, Selangor, D.E., MY |
| Contact | S.H. TAN |
| 510(k) history | 14 submissions · 14 cleared · 1998-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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