

**K050526 POLYMER COATED ONLINE CHLORINATED POWDER
FREE EXAMINATION GLOVES WITH PROTEIN LABELING
CLAIM (CONTAINS 50 MICROGRAMS OR**Dec 6, 2005
279 days to decisionK050526 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k050526/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 2, 2005 |
| Decision date | Dec 6, 2005 |
| Days to decision | 279 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Spi Gloves Sdn. Bhd. |
| Location | Ipoh 30450, MY |
| Contact | CHOOI FONG CHUN |
| 510(k) history | 7 submissions · 7 cleared · 2005-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050526/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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