

K010803 POWDER-FREE LATEX EXAMINATION GLOVES-BLUE COLOR

May 11, 2001
56 days to decision

K010803 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k010803/>

SUBMISSION DETAILS

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 16, 2001 |
| Decision date | May 11, 2001 |
| Days to decision | 56 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Hwa Teh Industrial Sdn. Bhd. |
| Location | Cerritos, CA, US |
| Contact | ABDUL HALIM ARSHAD |
| 510(k) history | 6 submissions · 6 cleared · 1989-2001 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k010803/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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