

K014230 STERILE POWDER FREE LATEX SURGEON GLOVES WITH PROTEIN LABELING CLAIM (50 MICROGRAM OR LESS)

Mar 13, 2002
77 days to decision

K014230 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k014230/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Dec 26, 2001 |
| Decision date | Mar 13, 2002 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Supermax Glove Manufacturing Sdn Bhd |
| Location | Selangor, MY |
| Contact | STANLEY THAI |
| 510(k) history | 6 submissions · 6 cleared · 2000-2003 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k014230/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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