

**K001274 LATEX SURGEON SURGEON'S GLOVES
POWDER-FREE WITH PROTEIN CONTENT LABELING CLAIM
(50 MICROGRAMS OR LESS)**

Jun 23, 2000
64 days to decision

K001274 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k001274/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Apr 20, 2000 |
| Decision date | Jun 23, 2000 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Pt. Maja Agung Latexindo |
| Location | Indonesia, ID |
| Contact | EMMY TJOENG |
| 510(k) history | 11 submissions · 11 cleared · 1990-2022 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k001274/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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