

K952589 ROYAL SHIELD PINK & BLUE COLORED NON-STERILE LATEX EXAMINATION GLOVESAug 11, 1995
67 days to decisionK952589 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k952589/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jun 5, 1995 |
| Decision date | Aug 11, 1995 |
| Days to decision | 67 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------------|
| Company | Shield Gloves Manufacturer (M) Sdn Bhd |
| Location | Petaling Jaya, MY |
| Contact | KATHERINE OOI |
| 510(k) history | 18 submissions · 18 cleared · 1994-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952589/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026