

**K943043 ROYAL SHIELD NON-STERILE LATEX EXAM GLOVES-
BUBBLE GUM**Sep 26, 1994
91 days to decisionK943043 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k943043/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jun 27, 1994 |
| Decision date | Sep 26, 1994 |
| Days to decision | 91 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/k943043/> 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