

K952588 ROYAL SHIELD NON-STERILE LATEX EXAMINATION GLOVESOct 12, 1995
129 days to decisionK952588 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k952588/>**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jun 5, 1995 |
| Decision date | Oct 12, 1995 |
| Days to decision | 129 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shield Gloves Manufacturer Sdn. Bhd. C/O Lentz, Inc. |
| Location | Selangor Darul Ehsan, MY |
| Contact | KATHERINE OOI |
| 510(k) history | 5 submissions · 5 cleared · 1989-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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