

K891389 PATIENT EXAMINATION GLOVES (LATEX)May 12, 1989
58 days to decision

K891389 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k891389/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 15, 1989 |
| Decision date | May 12, 1989 |
| Days to decision | 58 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rubberex (M) Sdn Berhad |
| Location | Perak, Malaysia, MY |
| Contact | SWEE KEH |
| 510(k) history | 2 submissions · 2 cleared · 1989-1989 |

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