FDA 510(k) Premarket Notification

# K891663 LEEDAR (PATIENT EXAMINATION GLOVES - LATEX)

**CLEARED**

Feb 13, 1990
330 days to decision

K891663 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k891663/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 20, 1989 |
| Decision date | Feb 13, 1990 |
| Days to decision | 330 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Darchet (Usa), Inc.** |
| Location | Monterey Park, CA, US |
| Contact | HENRY CHUANG |
| 510(k) history | 2 submissions · 2 cleared · 1990-1990 |