

K010875 HYCARE LATEX EXAMINATION GLOVE, POWDEREDJun 7, 2001
76 days to decision

K010875 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k010875/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 23, 2001 |
| Decision date | Jun 7, 2001 |
| Days to decision | 76 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Hycare Intl. Co., Ltd. |
| Location | Deerfield Beach, FL, US |
| Contact | JOHN GRASSI |
| 510(k) history | 3 submissions · 3 cleared · 2001-2002 |

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