

**K953379 HYPOALLERGENIC POWDERED AMBIDEXTROUS
COAGULATN DIPPED LATEX EXAMINATION GLOVE**Sep 27, 1995
70 days to decisionK953379 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k953379/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jul 19, 1995 |
| Decision date | Sep 27, 1995 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ansell, Inc. |
| Location | Dothan, AL, US |
| Contact | KAY SMITH |
| 510(k) history | 30 submissions · 30 cleared · 1980-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953379/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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