

K010961 X-TENDA CUFF POWDER FREE NON-STERILE LATEX EXAMINATION GLOVE WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)May 31, 2001
62 days to decisionK010961 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k010961/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 30, 2001 |
| Decision date | May 31, 2001 |
| Days to decision | 62 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ansell Healthcare Products, Inc. |
| Location | Massillon, OH, US |
| Contact | JAMES R CHATTERTON |
| 510(k) history | 10 submissions · 10 cleared · 2000-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010961/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026