

K945246 PREVENTOR AND PROTECTOR LATEX CONDOMSSep 7, 1995
315 days to decisionK945246 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k945246/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Oct 27, 1994 |
| Decision date | Sep 7, 1995 |
| Days to decision | 315 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | American Pharmaceutical Co., Inc. |
| Location | Walker, MI, US |
| Contact | ALFRED C BAGWELL |
| 510(k) history | 2 submissions · 2 cleared · 1981-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945246/> 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 29, 2026