

**K874464 SPERMICIDAL CONDOM**Nov 20, 1987  
25 days to decisionK874464 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k874464/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Condom (HIS)                       |
| Date received         | Oct 26, 1987                       |
| Decision date         | Nov 20, 1987                       |
| Days to decision      | 25 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|--|
| Company        | <b>Royal American Industries, Inc.</b> |
| Location       | Boca Raton, FL, US                     |
| Contact        | IRWIN VOLIN                            |
| 510(k) history | 2 submissions · 2 cleared · 1987-1987  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k874464/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026