

**K912901 TROJAN (TM-TBD) CONDOM**Feb 3, 1992  
216 days to decisionK912901 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k912901/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Condom (HIS)                       |
| Date received         | Jul 2, 1991                        |
| Decision date         | Feb 3, 1992                        |
| Days to decision      | 216 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Carter Products</b>                  |
| Location       | Cranbury, NJ, US                        |
| Contact        | STEPHEN KOLAKOWSKY                      |
| 510(k) history | 20 submissions · 20 cleared · 1988-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912901/> 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 29, 2026