

**K001212 TROJAN EXTRA LARGE LATEX CONDOM**May 9, 2000  
25 days to decisionK001212 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k001212/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Condom (HIS)                       |
| Date received         | Apr 14, 2000                       |
| Decision date         | May 9, 2000                        |
| Days to decision      | 25 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Armkel, LLC</b>                      |
| Location       | Mchenry, IL, US                         |
| Contact        | STEPHEN C KOLAKOWSKY                    |
| 510(k) history | 68 submissions · 68 cleared · 1979-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001212/> 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