

K901196 TROJAN FOR WOMEN LUBRI. CONDOMS MODIFIED LABELINGApr 16, 1990
35 days to decisionK901196 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k901196/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Mar 12, 1990 |
| Decision date | Apr 16, 1990 |
| Days to decision | 35 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Carter Products |
| Location | Cranbury, NJ, US |
| Contact | C KOLAKOWSKY |
| 510(k) history | 20 submissions · 20 cleared · 1988-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k901196/> 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