

K883413 TROJAN EXTRA STRENGTH LUBRICATEDDec 8, 1988
115 days to decisionK883413 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k883413/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Aug 15, 1988 |
| Decision date | Dec 8, 1988 |
| Days to decision | 115 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/k883413/>; 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