

K893953 ABSOLUTE(TM)-HCG URINE PREGNANCY TESTAug 15, 1989
75 days to decisionK893953 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k893953/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Human Chorionic Gonadotropin (DHA) |
| Date received | Jun 1, 1989 |
| Decision date | Aug 15, 1989 |
| Days to decision | 75 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Totem Diagnostics, Inc. |
| Location | Vancouver, B.C. V5z 4h5, CA |
| Contact | KING F HUI |
| 510(k) history | 1 submissions · 1 cleared · 1989-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893953/>; 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 July 2, 2026