

**K974425 BIOSIGN HCG-ONE STEP PREGNANCY TEST,
ACCUSIGN HCG-ONE STEP PREGNANCY TEST, LIFESIGN HCG-
ONE STEP PREGNANCY TEST**Dec 24, 1997
30 days to decisionK974425 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k974425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Nov 24, 1997
Decision date	Dec 24, 1997
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	JEMO KANG
510(k) history	72 submissions · 72 cleared · 1994-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974425/>; 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 May 25, 2026