

K941090 UNISTEP HCG PREGNANCY TEST STRIPJun 2, 1994
86 days to decisionK941090 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k941090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Mar 8, 1994
Decision date	Jun 2, 1994
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biotech Atlantic, Inc.
Location	Eatontown, NJ, US
Contact	YO YIH
510(k) history	4 submissions · 4 cleared · 1994-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941090/> 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