

**K964574 AFFIRM ONE-STEP PROFESSIONAL PREGNANCY TEST**Jan 21, 1997  
68 days to decisionK964574 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k964574/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 14, 1996
Decision date	Jan 21, 1997
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Athena Medical Corp.</b>
Location	Portland, OR, US
Contact	PATRICIA FEETHAM
510(k) history	2 submissions · 2 cleared · 1996-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964574/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated July 1, 2026